DOCKET

SUPREME COURT
OF THE UNITED STATES

No. 12-236
Title: Kathleen Sebelius, Secretary of Health and Human Services, Petitioner
v.
Melissa Cloer
Docketed: August 22, 2012
Linked with 11A1252
Lower Ct: United States Court of Appeals for the Federal Circuit
Case Nos.: (2009-5052)
Decision Date: April 11, 2012
Questions Presented

~~Date~~~	~~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~~~
Jun 27 2012	Application (11A1252) to extend the time to file a petition for a writ of certiorari from July 10, 2012 to August 9, 2012, submitted to The Chief Justice.
Jun 27 2012	Application (11A1252) granted by The Chief Justice extending the time to file until August 9, 2012.
Jul 27 2012	Application (11A1252) to extend further the time from August 9, 2012 to August 23, 2012, submitted to The Chief Justice.
Jul 27 2012	Application (11A1252) granted by The Chief Justice extending the time to file until August 23, 2012.
Aug 22 2012	Petition for a writ of certiorari filed. (Response due September 21, 2012)
Sep 5 2012	Order extending time to file response to petition to and including October 12, 2012.
Oct 9 2012	Order further extending time to file response to petition to and including October 29, 2012.
Oct 26 2012	Brief of respondent Melissa Cloer in opposition filed.
Nov 5 2012	DISTRIBUTED for Conference of November 20, 2012.
Nov 9 2012	Reply of petitioner Kathleen Sebelius, Secretary of Health and Human Services filed. (Distributed)
Nov 20 2012	Petition GRANTED.
Jan 4 2013	Brief of petitioner Kathleen Sebelius, Secretary of Health and Human Services filed.
Jan 4 2013	Joint appendix filed.
Jan 7 2013	SET FOR ARGUMENT ON Tuesday, March 19, 2013
Jan 23 2013	CIRCULATED.
Jan 25 2013	Received record from the U.S.C.A. for the Federal Circuit Court. (1 box)
Feb 4 2013	Brief of respondent Melissa Cloer filed. (Distributed)

Feb 11 2013	Brief amici curiae of Elizabeth Birt Center for Autism Law and Advocacy, et al. filed. (Distributed)
Feb 11 2013	Brief amici curiae of National Vaccine Information Center, et al. filed. (Distributed)
Mar 1 2013	Record from U.S. Court of Federal Claims is eletronic.
Mar 5 2013	Reply of petitioner Kathleen Sebelius, Secretary of Health and Human Services filed. (Distributed)
Mar 19 2013	Argued. For petitioner: Benjamin J. Horwich, Assistant to the Solicitor General, Department of Justice, Washington, D. C. For respondent: Robert T. Fishman, Denver, Colo.
May 13 2013	Letter from counsel for petitioner Kathleen Sebelius, Secretary of Health and Human Services filed. (Distributed)

PETITION FOR WRIT OF CERTIORARI

Supreme Court, U.S.
FILED
AUG 2 2 2012
OFFICE OF THE CLERK

12-236

No.

In the Supreme Court of the United States

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

MELISSA CLOER

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a person whose petition under the National Vaccine Injury Compensation Program is dismissed as untimely may recover from the United States an award of attorneys' fees and costs.

PARTIES TO THE PROCEEDING

The caption of the case in this Court contains the names of all parties in the court of appeals.

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In the Supreme Court of the United States

No.

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

MELISSA CLOER

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of Kathleen Sebelius, the Secretary of Health and Human Services, respectfully petitions for a writ of certiorari to review the order of the United States Court of Appeals for the Federal Circuit in this case.

ORDER AND OPINIONS BELOW

The order of the en banc court of appeals (App., *infra*, 1a-21a) is reported at 675 F.3d 1358. A related opinion of the en banc court of appeals (App., *infra*, 22a-83a) is reported at 654 F.3d 1322. A related opinion of a panel of the court of appeals (App., *infra*, 88a-125a) is reported at 603 F.3d 1341. A related opinion of the United States Court of Federal Claims (App., *infra*, 126a-154a) is reported at 85 Fed. Cl. 141. A related decision of the Chief Special Master of the United States

Court of Federal Claims (App., *infra*, 155a-176a) is not published in the *Federal Claims Reporter* but is available at 2008 WL 2275574.

JURISDICTION

The order of the en banc court of appeals was entered on April 11, 2012. On June 27, 2012, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including August 9, 2012. On July 27, 2012, the Chief Justice further extended the time to August 23, 2012. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The pertinent statutory provisions are reprinted in an appendix to this petition. App., *infra*, 177a-182a.

STATEMENT

This case presents the question whether a person whose petition under the National Vaccine Injury Compensation Program is dismissed as untimely may recover from the United States an award of attorneys' fees and costs. Dividing 7-to-6, the en banc Federal Circuit held that such awards are available.

1. To stabilize the vaccine market and provide compensation for vaccine-related injuries and deaths, Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), 42 U.S.C. 300aa-1 *et seq.* The Vaccine Act created the National Vaccine Injury Compensation Program (Compensation Program or Program), see 42 U.S.C. 300aa-10(a), which provides compensation for vaccine-related injuries and deaths through a no-fault system "designed to work faster and with greater ease than the civil tort system." *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011)

(quoting *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995)). Covered vaccines and injuries commonly associated with them are identified in a Vaccine Injury Table, and a causal connection between vaccine and injury is rebuttably presumed when a claim is based on an injury specified in the Table. *Whitecotton*, 514 U.S. at 270; 42 U.S.C. 300aa-14; 42 C.F.R. Pt. 100. If an injury falls outside the parameters of the Table, a claimant must establish that the injury "was caused by" the covered vaccine. 42 U.S.C. 300aa-11(c)(1)(C)(ii).

A person injured by a vaccine (or the representative of such a person) may file a petition for compensation in the United States Court of Federal Claims (CFC), naming the Secretary of Health and Human Services (Secretary) as respondent. *Bruesewitz*, 131 S. Ct. at 1073. A special master of the CFC then "makes an informal adjudication of the petition," *ibid.*, subject to further review by a judge of the CFC and by the United States Court of Appeals for the Federal Circuit, see 42 U.S.C. 300aa-12(e)(2)(B) and (f). "After judgment has been entered by the [CFC] or * * * after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa-11" must elect between accepting the CFC's judgment and pursuing a civil tort action instead. 42 U.S.C. 300aa-21(a).

The Vaccine Act provides in relevant part that "no petition may be filed for compensation under the Program * * * after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of" the alleged injury for which compensation is sought. 42 U.S.C. 300aa-16(a)(2). The Act also provides for awards of attorneys' fees and costs in certain circumstances:

> (1) In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover—
>
> (A) reasonable attorneys' fees, and
>
> (B) other costs,
>
> incurred in any proceeding on such petition. If the judgment of the [CFC] on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

42 U.S.C. 300aa-15(e)(1). Awards of attorneys' fees and costs, like awards of compensation on the merits, are paid from the Vaccine Injury Compensation Trust Fund, which is supported by an excise tax on each vaccine dose. See 42 U.S.C. 300aa-15(f)(4)(A); 26 U.S.C. 4131, 9510.

Section 300aa-15(e)(1) is the sole source of compensation for attorneys in the circumstances described. See 42 U.S.C. 300aa-15(e)(3) ("No attorney may charge any fee for services in connection with a petition filed under [42 U.S.C. 300aa-11] which is in addition to any amount awarded as compensation by the special master or court under [42 U.S.C. 300aa-15(e)(1)]."). Section 300aa-15(e)(1) differs from most fee-shifting provisions in that it does not make success on the underlying claim a prerequisite to an award of fees. Rather, so long as

the special master or the court finds that a petition under Section 300aa-11 "was brought in good faith and there was a reasonable basis for the claim," the special master or the court may award attorneys' fees and costs even "[i]f the judgment * * * does not award compensation" to the claimant. 42 U.S.C. 300aa-15(e)(1).

2. After receiving three Hepatitis-B immunizations in 1996 and 1997, respondent experienced in mid-1997 what proved to be her first symptom of multiple sclerosis (MS). App., *infra*, 29a. In 2005, eight years after her first symptoms of MS, respondent filed a claim for compensation under the Vaccine Act. *Id.* at 31a. The special master dismissed her claim as time-barred (*id.* at 155a-176a), and the CFC affirmed (*id.* at 126a-154a).

3. a. A divided panel of the Federal Circuit reversed. App., *infra*, 88a-125a. The panel held that the Vaccine Act's limitations period does not begin to run until there is objective medical recognition of a link between the claimed injury and the vaccine. *Id.* at 93a-102a. In respondent's case, the panel concluded, such recognition had occurred (if at all) no earlier than 2004. *Id.* at 102a.

b. The court of appeals granted the government's petition for rehearing en banc and affirmed the CFC's dismissal of respondent's claim as time-barred. App., *infra*, 22a-83a. The en banc court rejected the panel's view that the Vaccine Act's statute of limitations is not triggered unless there is a medical recognition of a link between the claimed injury and the vaccine. The court held instead that, "[c]onsistent with the plain meaning of the statute, * * * the statute of limitations of the Vaccine Act begins to run on the calendar date of the occurrence of the first medically recognized symptom or

manifestation of onset of the injury claimed by the petitioner." *Id.* at 23a-24a.

The en banc court of appeals further held that the Vaccine Act's statute of limitations is subject to equitable tolling, but that respondent had failed to identify a sound basis for tolling in her case. App., *infra*, 24a. Focusing on traditional circumstances warranting equitable tolling, the court explained that respondent "has put no argument before this court that, for example, she has been the victim of a fraud, or of duress." *Id.* at 65a. Respondent contended that applying the Act's time limits "is *ipso facto* unfair because it threatens to deprive her of her claim." *Ibid.* The court concluded that this was "not * * * the sort of circumstance that might merit equitable tolling." *Ibid.*

c. This Court denied respondent's petition for a writ of certiorari seeking review of the court of appeals' holding that her claim was time-barred. 132 S. Ct. 1908 (No. 11-832).

4. Respondent moved in the court of appeals for an award of $118,792.95 in attorneys' fees and costs for proceedings in the Federal Circuit. App., *infra*, 4a; *Cloer* v. *Secretary of HHS*, No. 2009-5052, Docket entry No. 79 (Fed. Cir. Sept. 6, 2011) (application for award of attorneys' fees and costs); *id.* Docket entry No. 75 (Sept. 12, 2011) (supplement to application). By a 7-6 vote, the court of appeals held that the dismissal of respondent's complaint as untimely did not preclude the possibility of a fee award under the Act. The court remanded for a determination whether respondent's claim had been brought in good faith and with a reasonable basis. App., *infra*, 1a-12a.

a. Seven members of the en banc court of appeals held that a person who files an untimely Vaccine Act

petition, but who "assert[s] a reasonable limitations argument" in connection with that claim, is eligible for an award of attorneys' fees and costs "absent a determination that [the] petition was not brought in good faith or that the claim for which the petition was brought lacked a reasonable basis." App., *infra*, 5a. The majority held "that Congress did not intend to require compliance with [42 U.S.C.] 300aa-16 as a prerequisite for the recovery of attorneys' fees." *Id.* at 6a. Rather, the majority concluded, "[t]he good faith and reasonable basis requirements apply to the claim for which the petition was brought; this applies to the entire claim, including timeliness issues." *Id.* at 9a.

The en banc majority recognized that, under 42 U.S.C. 300aa-15(e), a Vaccine Act fee award is available only in a case involving "a petition filed under section 300aa-11 of this title." App., *infra*, 6a. It also acknowledged the directive in 42 U.S.C. 300aa-16(a) that "no petition may be filed for compensation under the Program" after the Act's limitations period has expired. App., *infra*, 10a. The majority concluded, however, that for purposes of the Vaccine Act's attorneys' fees provision, an untimely petition qualifies as a "a petition filed under [42 U.S.C. 300aa-11]." *Id.* at 6a-7a.

In support of that conclusion, the en banc majority observed that Vaccine Act proceedings can be initiated only by the filing of a petition. App., *infra*, 5a (citing 42 U.S.C. 300aa-11(a)(1)). The majority inferred from that fact that "[u]nless * * * [respondent's] filing was a 'petition filed,' neither we nor the [CFC] had jurisdiction over her appeal." *Ibid.* The majority also explained that another provision of the Vaccine Act (42 U.S.C. 300aa-11(a)(2)(A), relating to the conditions for filing a civil suit under state law) expressly cross-references the

limitations provision. App., *infra*, 6a. The majority stated that "[t]he absence of an analogous reference to [42 U.S.C.] 300aa-16 in the attorneys' fees provision suggests that Congress did not intend to require compliance with [42 U.S.C.] 300aa-16 as a prerequisite for the recovery of attorneys' fees." *Ibid.* The majority also noted that the term "petition filed" is used in other Vaccine Act provisions and, in context, appears to encompass untimely petitions. *Id.* at 6a-7a.

The en banc majority also stated that "[r]emedial legislation like the Vaccine Act should be construed in a manner that effectuates its underlying spirit and purpose." App., *infra*, 8a. The majority expressed the view that its interpretation of the Act's fee provision would "fulfill[] congressional intent and the Act's legislative purpose" because "having to shoulder attorneys' fees could deter victims of vaccine-related injuries from seeking redress." *Ibid.* The court of appeals remanded to the CFC for a determination "whether [respondent's] petition was brought in good faith and whether the claim for which her petition was brought had a reasonable basis." *Id.* at 12a.

b. Judge Bryson, writing for six judges, dissented. App., *infra*, 13a-21a. He explained that "[42 U.S.C. 300aa-16(a)] directs that 'no petition may be filed for compensation under the Program'—and thus under [42 U.S.C. 300aa-11]—after the expiration of the applicable time period." App., *infra*, 14a. He further observed that "[42 U.S.C. 300aa-15(e)(1)] allows an attorneys' fee award only when a petition is filed under [42 U.S.C. 300aa-11]." App., *infra*, 14a. The dissenting judges would have held on that basis that "an attorneys' fee award may be made only if the claimant files a timely petition, either by satisfying the applicable limitations

period of [42 U.S.C. 300aa-16] or successfully invoking equitable tolling." App., *infra*, 14a (citations omitted).

Judge Bryson noted as well that "it is almost unknown in American practice for a statute to provide that the prevailing party will pay the losing party's attorneys' fees." App., *infra*, 18a. He reasoned that, "because Congress departed from the governing principles applied in virtually every other federal fee-shifting statute, [the court] should be cautious in interpreting the statutory mandate to extend beyond those cases in which fee-shifting was clearly intended." *Id.* at 19a.

Judge Bryson also expressed concern about the practical difficulties that would arise in deciding a claim for attorneys' fees in a case dismissed on threshold timeliness grounds. He explained that, because Vaccine Act fees are available only for petitions brought in good faith and with a reasonable basis, the special master would be required to conduct "a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding." App., *infra*, 20a. He observed that "[q]uite apart from the burden on the special masters and the court, the amount of attorney time (and thus the accumulating fees) that would be consumed by such a proceeding would likely exceed the fees expended on the typically much simpler question whether equitable tolling is available to the claimant." *Id.* at 20a-21a. Judge Bryson reasoned that "it seems unlikely that Congress envisioned such a scheme, and in the absence of express congressional authorization, we should be cautious about engrafting one onto the statute." *Id.* at 21a.

REASONS FOR GRANTING THE PETITION

By a 7-6 margin, the en banc Federal Circuit held that the United States is liable to pay the attorneys' fees of certain Vaccine Act claimants whose petitions for compensation do not even meet the Act's threshold timeliness requirement. That result departs from the Act's text and structure, it ignores applicable canons of statutory construction, and it threatens the efficient functioning of the Compensation Program. As the en banc majority recognized, the question whether fees may be awarded on untimely petitions "will frequently arise in vaccine injury cases." App., *infra*, 11a. Because the Federal Circuit has exclusive jurisdiction to decide the question presented, no circuit conflict is possible. This Court should grant review and correct the Federal Circuit's error.

A. The Federal Circuit Erred In Holding That A Vaccine Act Claimant Whose Petition For Compensation Is Dismissed As Untimely May Recover From The United States An Award Of Attorneys' Fees And Costs

Under the most straightforward reading of the Vaccine Act's limitations and attorneys' fees provisions, an award of attorneys' fees and costs is unavailable when a petition is dismissed as time-barred. The cumbersome regime that results from the court of appeals' contrary holding—under which a special master must conduct "a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding," App., *infra*, 20a (Bryson, J., dissenting)—is an obvious structural mismatch for a compensation system "designed to work faster and with greater ease than the civil tort system." *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011)

(quoting *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995)). Applicable canons of statutory construction reinforce the conclusion that fee awards are unavailable in these circumstances.

1. The court of appeals misinterpreted the text and structure of the Vaccine Act

a. The Vaccine Act requires the special master to award attorneys' fees and costs when "awarding compensation on a petition filed under section 300aa-11 of this title." 42 U.S.C. 300aa-15(e)(1). The Act permits (but does not require) a similar award of fees and costs "[i]f the judgment * * * on *such a petition* does not award compensation." *Ibid.* (emphasis added). Because the phrase "such a petition" refers back to "a petition filed under section 300aa-11 of this title," the court of appeals' decision in this case depends on the court's determination that an untimely Vaccine Act petition is a "petition filed under [42 U.S.C. 300aa-11]."

The Vaccine Act's limitations provision states, however, that "if a vaccine-related injury occurred as a result of the administration of [a covered] vaccine, *no petition may be filed* for compensation under the Program for such injury" after the expiration of the applicable time period. 42 U.S.C. 300aa-16(a)(2) (emphasis added). Because compliance with the limitations provision is a statutory prerequisite to the filing of a petition "for compensation under the Program," a petition that has been dismissed for failure to comply with the Act's time limits is not a "petition filed under [42 U.S.C. 300aa-11]." And in the absence of a petition filed under 42 U.S.C. 300aa-11, there is no statutory basis for awarding attorneys' fees and costs. See App., *infra*, 14a (Bryson, J., dissenting).

b. The result reached by the majority below is also incompatible with the structure and overall purpose of the Vaccine Act. Congress sought to establish a simple and efficient procedural mechanism for providing compensation to persons injured by vaccines. The court of appeals' decision, by contrast, will necessitate complex proceedings that cannot possibly result in compensation for injured persons.

In a case in which the judgment does not award compensation, a fee award is authorized only for a claim "brought in good faith" and with a "reasonable basis." 42 U.S.C. 300aa-15(e)(1). As Judge Bryson explained in dissent, "[i]n a case that has gone to judgment on the merits and the [Vaccine Act] petitioner has lost, it is fairly easy for the special master and the court to determine whether the petitioner's position on the merits was reasonable," because "the special master and the court will have the entire record of the case before them to enable them to make that determination." App., *infra*, 20a. The special master who has studied and resolved the pertinent merits issues can apply the knowledge acquired during that endeavor in deciding whether an award of attorneys' fees and costs is warranted. The special master is thus in a position similar to that of a district judge who has decided a case on the merits adversely to the government, and is therefore well-positioned to determine whether the government's position was "substantially justified" under the Equal Access to Justice Act (EAJA), 28 U.S.C. 2412(d). See *Pierce* v. *Underwood*, 487 U.S. 552, 560 (1988) (noting that a district judge deciding a request for EAJA fees has "full knowledge of the factual setting" and, by dint of experience with the case, "may have insights not conveyed by the record").

By contrast, a Vaccine Act petition submitted after the Act's limitations period has expired may be dismissed on threshold grounds without any meaningful analysis of the merits. When that occurs, the special master will have amassed no record, and will have acquired no case-specific expertise, that can be used to determine whether the claim was brought in "good faith" and had a "reasonable basis" on the merits. 42 U.S.C. 300aa-15(e)(1). To decide whether the claimant could satisfy those statutory prerequisites for a fee award, the special master therefore would be required to "conduct a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding." App., *infra*, 20a (Bryson, J., dissenting).

Such a collateral proceeding would be wasteful, painful, and complex—the antithesis of the system that Congress "designed to work faster and with greater ease than the civil tort system." *Bruesewitz*, 131 S. Ct. at 1073 (quoting *Whitecotton*, 514 U.S. at 269). Proceedings to decide whether there was a reasonable basis for a claim (had it been timely) would consume much of the effort that actually deciding the claim would have entailed, undermining the resource-conserving purpose of the limitations provision. Such proceedings would typically include review of the claimant's medical records, development of expert testimony, and briefing to the special master. Cf., *e.g.*, *Perreira* v. *Secretary of HHS*, 33 F.3d 1375, 1377 (Fed. Cir. 1994) (applying the "reasonable basis" requirement in an objective fashion taking into account the evidence offered in support of the Vaccine Act petitioner's merits claim). In cases where the special master held that a fee award was appropriate, the award could include attorneys' fees and costs for

the fee proceedings themselves. See App., *infra*, 20a-21a (Bryson, J., dissenting) (predicting that the amount of attorney time and consequent fees attributable to fee proceedings in this situation typically will be greater than the fees incurred while litigating the original timeliness question). That effort and those expenses, moreover, would be incurred *after* it had been definitively determined that the claimant was not entitled to compensation.

This shadow trial would be thoroughly unappealing to the claimant herself. Vaccine Act claimants often suffer from debilitating diseases or conditions that require lifelong intensive medical care and are sometimes terminal. Yet the attorneys' fee inquiry would call on the claimant to further expose her medical records (and perhaps herself) to expert examination, and face a trial of sorts. To be sure, a claimant who seeks Vaccine Act compensation must accept similar burdens in connection with the resolution of her claim on the merits. But while such merits proceedings may culminate in an actual award of compensation, the shadow trial necessitated by the decision below can produce no tangible benefit for the claimant herself, only for her lawyer.

Moreover, the determination whether a claimant had reasonable arguments as to both timeliness and the merits can be particularly delicate and complex in Vaccine Act cases because there will sometimes be tension between a claimant's merits and timeliness theories. To establish that a particular medical condition resulted from administration of a covered vaccine, it is typically helpful to show that the first manifestations of the condition were perceived soon after the vaccine was administered. See, *e.g.*, *Althen* v. *Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (explaining that a "showing

of a proximate temporal relationship between vaccination and injury" tends to support a claim under the Vaccine Act). But because the Vaccine Act's limitations period begins to run on "the date of the occurrence of the first symptom or manifestation of onset" of the pertinent condition, 42 U.S.C. 300aa-16(a)(2), a claimant's effort to establish the reasonableness of her position with regard to timeliness will often involve an attempt to dispute the relevance of any early-occurring symptom. Thus, in considering a fee request after dismissal of an untimely Vaccine Act petition, a special master would need to determine not only whether the claimant had reasonable arguments on both timeliness and the merits, but also whether those arguments were internally consistent.

The facts of *Smith* v. *Secretary of HHS*, No. 02-93V, 2006 WL 5610517 (Fed. Cl. July 21, 2006), sustained, 2006 WL 5624674 (Fed. Cl. Nov. 16, 2006), aptly illustrate the problem the court of appeals' decision creates. There, the Vaccine Act petitioner alleged that her son had developed diabetes as a result of a series of vaccinations ending in late 1998. *Id.* at *1-*2. In January 1999, the boy experienced symptoms including excessive thirst and frequent urination. *Id.* at *2, *6. In February 1999, the boy was hospitalized with dangerously high blood sugar and diagnosed with diabetes. *Id.* at *2. The Vaccine Act petition was filed in late January 2002, within the 36-month limitation period as measured from the hospitalization and diagnosis of diabetes, but outside the period as measured from the earlier symptoms. *Id.* at *2-*3. The claim was held to be time-barred, based on the special master's finding that the earlier symptoms were "the first symptom or manifestation of onset," 42 U.S.C. 300aa-16(a)(2), of the boy's diabetes. 2006 WL 5610517, at *7.

Under the decision below, resolving whether the claimant was entitled to an award of attorneys' fees and costs would entail a collateral proceeding to determine whether there was a reasonable basis for believing that the boy's vaccinations in 1998 caused diabetes that was first manifested in February 1999, with coincidental and unrelated symptoms of excessive thirst and frequent urination in January 1999. That inquiry is substantially more complex than the inquiry called for if the claim had been timely (*viz.*, simply whether there was a reasonable basis for a claim that the boy's vaccinations caused his diabetes). "[I]t seems unlikely that Congress envisioned such a scheme, and in the absence of express congressional authorization," the court of appeals should not have "engraft[ed] one onto the statute." App., *infra*, 21a (Bryson, J., dissenting).

2. Applicable canons of statutory construction reinforce the conclusion that attorneys' fees are not available when a Vaccine Act petition is dismissed as untimely

For the foregoing reasons, the court of appeals' decision is inconsistent with the text and structure of the Vaccine Act. To the extent that any ambiguity remains, established canons of statutory construction should inform this Court's understanding of the Act's fee-shifting provision. Three such canons reinforce the conclusion that fees are not available when a Vaccine Act petition is dismissed as untimely.

First, the Vaccine Act authorizes monetary claims against the United States by way of a suit against the Secretary in her official capacity. "Caution is especially warranted in a case authorizing a monetary award against the government in light of well-settled principles of sovereign immunity." App., *infra*, 21a (Bryson, J.,

dissenting). That principle applies even when (as in the Vaccine Act) Congress has unambiguously waived sovereign immunity from *some* monetary claims. See, *e.g.*, *FAA* v. *Cooper*, 132 S. Ct. 1441, 1448 (2012) ("For the same reason that we refuse to enforce a waiver that is not unambiguously expressed in the statute, we also construe any ambiguities in the scope of a waiver in favor of the sovereign."). Accordingly, the scope of the Vaccine Act's waiver of sovereign immunity—including the United States' liability to pay respondent's attorneys' fees and costs—should be strictly construed. *E.g.*, *United States* v. *Nordic Vill. Inc.*, 503 U.S. 30, 34 (1992) ("[T]he Government's consent to be sued must be construed strictly in favor of the sovereign and not enlarged beyond what the language requires.") (alterations, citations, and internal quotation marks omitted).

Second, "statutes which invade the common law . . . are to be read with a presumption favoring the retention of long-established and familiar principles, except when a statutory purpose to the contrary is evident." *United States* v. *Texas*, 507 U.S. 529, 534 (1993) (citation omitted). In certain respects, the Vaccine Act's remedial provisions unambiguously deviate from prevailing legal practices. The very existence of a fee-shifting provision reflects a departure from the "American Rule," under which each party pays its own fees, *e.g.*, *Alyeska Pipeline Serv. Co.* v. *Wilderness Soc'y*, 421 U.S. 240, 247 (1975), and the Vaccine Act's fee-shifting provision is especially unusual because it does not make success on the merits a prerequisite to an award of fees. See App., *infra*, 18a (Bryson, J., dissenting) ("[I]t is almost unknown in American practice for a statute to provide that the prevailing party will pay the losing party's attorneys' fees."). Thus, even as construed by the govern-

ment and by the dissenting members of the en banc court of appeals, Section 300aa-15(e)(1) exposes the United States to much more expansive potential fee liability than does the typical federal statute. That fact counsels particular hesitation before reading Section 300aa-15(e)(1) to authorize fee awards in additional situations that the provision does not clearly cover. See *id.* at 19a ("[B]ecause Congress departed from the governing principles applied in virtually every other federal fee-shifting statute, [the courts] should be cautious in interpreting the statutory mandate to extend beyond those cases in which fee-shifting was clearly intended.").

Third, this Court has cautioned that ambiguous language in federal fee-shifting provisions should be construed, when the text of the statute permits, to limit the length and complexity of fee litigation. In *Pierce*, the Court concluded that "the text of the statute permits, and sound judicial administration counsels, deferential review of a district court's decision regarding attorney's fees under the EAJA." 487 U.S. at 563. The Court based that conclusion in part on the assessment that a deferential approach "will implement [the Court's] view that a 'request for attorney's fees should not result in a second major litigation.'" *Ibid.* (quoting *Hensley* v. *Eckerhart*, 461 U.S. 424, 437 (1983)).

That principle is directly applicable here. In a case where the special master has already conducted the inquiry needed to reject a Vaccine Act claim on the merits, the further determination whether the petition was brought in good faith and with a reasonable basis can typically be made in an expeditious manner. By contrast, when a Vaccine Act petition has been dismissed as untimely, the determination required by 42 U.S.C. 300aa-15(e)(1) will often require fee litigation of a length

and complexity that outstrips the underlying proceedings. See App., *infra*, 20a-21a (Bryson, J., dissenting); pp. 12-16, *supra*.

3. The reasons given for the en banc majority's holding are unpersuasive

The court of appeals' resistance to the most natural construction of the Act's fee-shifting provision rests principally on indirect inferences from other parts of the statute. Those inferences are unpersuasive even on their own terms.

a. The majority below first noted that, whereas a different Vaccine Act provision (42 U.S.C. 300aa-11(a)(2)(A)) contains a cross- reference to Section 300aa-16's limitations provision, the Act's fee-shifting provision does not. App., *infra*, 6a. The court inferred that "[t]he absence of an analogous reference to [42 U.S.C.] 300aa-16 in the attorneys' fees provision suggests that Congress did not intend to require compliance with [42 U.S.C.] 300aa-16 as a prerequisite for the recovery of attorneys' fees." *Ibid.* By its terms, however, the fee-shifting provision requires "a petition filed under section [42 U.S.C.] 300aa-11 of this title," see 42 U.S.C. 300aa-15(e)(1), and the limitations provision states that "no petition may be filed for compensation under the Program" after the expiration of prescribed time periods, 42 U.S.C. 300aa-16(a)(2). The fee-shifting provision's requirement of "a petition filed under [42 U.S.C.] 300aa-11" thus obviates the need for any direct cross-reference to the limitations provision itself. Cf. *Astrue* v. *Capato*, 132 S. Ct. 2021, 2031 (2012) ("Respondent notes the absence of any cross-reference in § 416(e) to § 416(h). She overlooks, however, that § 416(h) provides the crucial link * * * [by making] reference to 'this

subchapter' [which] includes * * * [§] 416(e). Having explicitly complemented § 416(e) by the * * * provisions contained in § 416(h), Congress had no need to place a redundant cross-reference in § 416(e).") (citation omitted).

b. The court of appeals was also wrong in stating that "[u]nless * * * [respondent's] filing was a 'petition filed,' neither we nor the [CFC] had jurisdiction over her appeal." App., *infra*, 5a. For two reasons, holding that a time-barred claim is not a "petition filed under section 300aa-11" would create no "jurisdictional impasse." *Id.* at 14a & n.1 (Bryson, J., dissenting). First, any court involved would have "jurisdiction to determine its jurisdiction." *Harmon* v. *Brucker*, 355 U.S. 579, 582 (1958) (per curiam). Second, 42 U.S.C. 300aa-12(a) alleviates the majority's specific concern by giving special masters broad jurisdiction "over proceedings to determine if a petitioner under [42 U.S.C. 300aa-11] is entitled to compensation under the Program." That authority logically includes the power to decide whether the claimant "is eligible under [42 U.S.C. 300aa-16] to file a petition for compensation." App., *infra*, 14a n.1 (Bryson, J., dissenting) (quoting 42 U.S.C. 300aa-12(a)).

c. The court of appeals also expressed concern that if the phrase "petition filed under section 300aa-11" is understood to exclude time-barred petitions, the Secretary and special masters will be unable to perform various statutory obligations with respect to "petitions filed" under the Act "until a determination is made as to the timeliness of the petition." App., *infra*, 6a-7a. But the obligations to which the court referred apply at the commencement of the action, when the claimant's allegations are taken as true and treated as sufficient to warrant further proceedings. For purposes of those require-

ments, a Vaccine Act petition can appropriately be treated as timely until the special master has definitively made a contrary determination. That is no different from ordinary litigation, in which, "[a]t the pleading stage, general factual allegations * * * may suffice," even though "at the final stage, those facts (if controverted) must be supported adequately by the evidence." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (internal quotation marks and citations omitted).

d. The en banc majority also believed its decision to be supported by prior Federal Circuit decisions (see, *e.g.*, *Shaw* v. *Secretary of HHS*, 609 F.3d 1372 (2010)) holding that "interim" fees may be awarded in Vaccine Act cases before the entry of judgment on the merits. The court stated: "Holding that attorneys' fees are only available where a petition has been subjected to a final adjudication on the merits is also inconsistent with the recognized practice of awarding interim attorneys' fees, which by definition does not require a final adjudication on the merits." App., *infra*, 10a-11a. For two reasons, prior Federal Circuit decisions allowing interim fees in Vaccine Act cases provide no sound basis for the decision below.

First, the Federal Circuit precedents allowing interim fees cannot be reconciled with the statutory text. The Vaccine Act authorizes the special master or court to award attorneys' fees either "[i]n awarding compensation on a petition filed under section 300aa-11" or, under certain circumstances, "[i]f the judgment of the [CFC] on such a petition does not award compensation." 42 U.S.C. 300aa-15(e)(1). Neither of those statutory conditions for a fee award—*i.e.*, an award of compensation, or a judgment that does not award compensation—can be satisfied until the claimant's entitlement to

compensation for the underlying injury has been finally adjudicated.

Second, even if interim fee awards were proper, that would be no reason to conclude that attorneys' fees could be awarded on untimely petitions. The Federal Circuit's initial opinion recognizing the possibility of "interim fees" in a Vaccine Act case rested in part on the court's perception that "[a] special master can often determine at an early stage of the proceedings whether a claim was brought in good faith and with a reasonable basis." *Avera* v. *Secretary of HHS*, 515 F.3d 1343, 1352 (2008). Thus, while the Federal Circuit has held that the Vaccine Act permits some fee awards before the entry of judgment, *Shaw*, 609 F.3d at 1374-1375, the special master must still acquire sufficient familiarity with the underlying facts to determine whether the "good faith" and "reasonable basis" requirements are satisfied. By the same token, the attorneys' fees provision's requirement of "a petition filed under section 300aa-11," 42 U.S.C. 300aa-15(e)(1), makes the availability of a Vaccine Act fee award—interim or otherwise—contingent on the timely submission of a claim. See p. 11, *supra*. Even if interim fee awards under the Vaccine Act were permissible in some circumstances, they could not properly be made without a finding that the petition was timely filed. The Federal Circuit's "interim fee" decisions accordingly provide no support for the proposition that fees may be awarded even after a petition has been determined to be untimely.

e. Finally, the majority below stated that "[r]emedial legislation like the Vaccine Act should be construed in a manner that effectuates its underlying spirit and purpose." App., *infra*, 8a. On that basis the court concluded that awards of attorneys' fees and costs for un-

timely petitions were appropriate because withholding such awards "could deter victims of vaccine-related injuries from seeking redress." *Ibid.* The general proposition underlying the court of appeals' reasoning is unhelpful in deciding this case because "[n]o legislation pursues its purposes at all costs, and [e]very statute purposes, not only to achieve certain ends, but also to achieve them by particular means." *Freeman* v. *Quicken Loans, Inc.*, 132 S. Ct. 2034, 2044 (2012) (second pair of brackets in original) (internal quotation marks and citations omitted). Here, the relevant provisions of the Vaccine Act obviously limit the availability of a claimant's remedies; the question is in what particular ways are those remedies limited. The statute of limitations bars untimely claims, irrespective of merit. And although the inducement of an award of attorneys' fees and costs was part of Congress's remedial design, such awards are undisputedly available only in proper circumstances, *i.e.*, on a successful petition or an unsuccessful petition filed in good faith with a reasonable basis. See 42 U.S.C. 300aa-15(e)(1). This case simply calls for recognition that timely filing is among the several conditions Congress placed on the availability of an award of attorneys' fees and costs.

B. The Court Of Appeals' Decision Threatens Significant Adverse Consequences For The Compensation Program

"[C]hallenges brought on limitations grounds will frequently arise in vaccine injury cases." App., *infra*, 11a. The court of appeals' decision can be expected to have two broad and adverse effects on the Compensation Program. Those consequences are sufficiently serious to warrant this Court's intervention.

First, the "shadow trials" described above, pp. 12-16, *supra*, can be expected to consume substantial resources of the special masters, reviewing courts, and others involved in the Compensation Program. Because a Vaccine Act petition may be dismissed as untimely before the special master has acquired substantial familiarity with the underlying facts, the fee proceedings in such cases are likely to be more elaborate and time-consuming than in cases where judgment has been entered on the merits. That is a particularly unwarranted and wasteful allocation of the Compensation Program's resources because the cases affected by the Federal Circuit's holding are by definition cases in which the claimant will not receive compensation. "A request for attorney's fees should not result in a second major litigation." *Hensley*, 461 U.S. at 437. But the Federal Circuit's decision promises exactly that.

Second, the inducement of a fee award to claimants' counsel is likely to increase the number of untimely Vaccine Act petitions. To be sure, the extent of that increase cannot reliably be predicted in advance. The basic purpose of fee-shifting provisions, however, is to increase the incentives for attorneys to provide services in particular categories of cases, thereby enhancing the ability of potential litigants to obtain representation. See, *e.g.*, *Pennsylvania* v. *Delaware Valley Citizens' Council for Clean Air*, 478 U.S. 546, 559-560 (1986). An increase in the number of untimely Vaccine Act petitions would therefore be the natural and expected result of the Federal Circuit's holding that attorneys who file such petitions are eligible for an award of fees.

Because the Program's resources are limited—there is, for example, a statutory cap on the number of special masters, 42 U.S.C. 300aa-12(c)(1)—effort devoted to

collateral matters tends to impede the prompt resolution of meritorious claims for much-needed compensation. By expanding the resources that special masters, reviewing courts, and others must devote to fee litigation and untimely claims, rather than to the merits of timely filed petitions, the court of appeals' decision subverts Congress's effort to establish a compensation system "designed to work faster and with greater ease than the civil tort system." *Bruesewitz*, 131 S. Ct. at 1073; see H.R. Rep. No. 908, 99th Cong., 2d Sess. 3 (1986) (explaining that the Act establishes a "compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity"); *id.* at 17 ("[M]uch of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the [Vaccine Act] petitioner can expect judgment," and "without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner"). The court of appeals' decision gravely disserves that purpose and should be corrected.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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AUGUST 2012

APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT-APPELLEE

Apr. 11, 2012

ORDER

Appeal from the United States Court of Federal Claims in 05-VV-1002, Judge Lawrence J. Block

ON APPLICATION FOR ATTORNEYS FEES AND COSTS

Before: RADER, *Chief Judge*, NEWMAN, LOURIE, CLEVENGER, BRYSON, GAJARSA,* LINN, DYK, PROST, MOORE, O'MALLEY, REYNA, and WALLACH, *Circuit Judges*.

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* Judge Gajarsa assumed senior status on July 31, 2011.

Opinion for the Court filed by *Circuit Judge* REYNA, in which *Circuit Judges* NEWMAN, LINN, DYK, MOORE, O'MALLEY, and WALLACH join.

Dissenting opinion filed by *Circuit Judge* BRYSON, in which *Chief Judge* RADER and *Circuit Judges* LOURIE, CLEVENGER, GAJARSA, and PROST join.

REYNA, *Circuit Judge*.

Dr. Melissa Cloer sought compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act"), alleging that her Hepatitis B vaccination caused her multiple sclerosis ("MS"). The Chief Special Master dismissed her petition as untimely, and the United States Court of Federal Claims affirmed. Dr. Cloer appealed, and although she did not ultimately prevail on the merits of her Vaccine Act claim, her appeal prompted a change of law in a limited way that potentially opens the door to certain Vaccine Act petitioners who otherwise would have been precluded from seeking redress.

The court must now decide whether Dr. Cloer is eligible to receive an award of reasonable attorneys' fees and costs in connection with her appeal. The Vaccine Act provides for the recovery of attorneys' fees "on a petition filed under section 300aa-11" when "the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought." 42 U.S.C. § 300aa-15(e)(1). We believe that a petitioner who asserts an unsuccessful but non-frivolous limitations argument should be eligible for a determination of whether reasonable attorneys' fees and costs incurred in proceedings related to the petition should be awarded. Therefore, we hold that the court has discretion to re-

mand for a determination of whether Dr. Cloer should be awarded reasonable attorneys' fees and costs.

I. BACKGROUND

Dr. Cloer was vaccinated for Hepatitis B in 1996 and 1997. Soon thereafter, she developed symptoms of MS. At that time, the medical literature was silent as to any connection between the Hepatitis B vaccination and MS. Several years later, Dr. Cloer learned of such a potential connection for the first time. By then her MS had significantly progressed.

Dr. Cloer filed a petition for compensation under the Vaccine Act. The Chief Special Master dismissed her petition as untimely because it was filed more than 36 months after her first symptom of MS had occurred, and the Court of Federal Claims affirmed. *Cloer v. Sec'y of Health & Human Servs.*, 85 Fed. Cl. 141 (2008). Dr. Cloer appealed, and a panel of this court reversed and remanded, ruling that her petition was not time-barred. *Cloer v. Sec'y of Health & Human Servs.*, 603 F.3d 1341 (Fed. Cir. 2010), *vacated*, 399 F. App'x 577 (Fed. Cir. 2010).

Due to the importance of the issues raised by Dr. Cloer, we granted the government's petition for rehearing en banc to determine the applicability of the statute of limitations to Dr. Cloer's case. *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322 (Fed. Cir. 2011) (en banc). In *Cloer*, we held that the Vaccine Act's statute of limitations is not jurisdictional and that some claims brought under the Vaccine Act are subject to equitable tolling. *Id.* at 1344. The court rejected a discovery rule but concluded that Dr. Cloer's claim does not meet those equitable tolling criteria and dismissed her petition as untimely. *Id.* at 1340, 1344-45. Prior to

Cloer, courts treated § 300aa-16(a)(2) as jurisdictional, and applications for attorneys' fees related to time-barred petitions were dismissed for lack of jurisdiction. In other words, if a petition was untimely, there was no jurisdiction. *Cloer* rejected that jurisdictional theory.

Dr. Cloer requested an award of reasonable attorneys' fees and costs incurred in her appeal. The government opposed her request on the ground that the Vaccine Act does not permit such an award in connection with a time-barred claim.

II. Discussion

The Vaccine Act establishes the criteria to be considered in determining whether a petitioner is eligible for attorneys' fees. Section 300aa-15(e) provides:

> (1) In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover—
>
> (A) reasonable attorneys' fees, and
>
> (B) other costs,
>
> *incurred in any proceeding* on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs *incurred in any proceeding* on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(emphasis added). In sum, attorneys' fees are available where the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

This court has not conducted a good faith and reasonable basis analysis of Dr. Cloer's claim; nor did it require the Special Master or Court of Federal Claims to conduct such an analysis. Dr. Cloer asserted a reasonable limitations argument, and absent a determination that her Vaccine Act petition was not brought in good faith or that the claim for which the petition was brought lacked a reasonable basis, she should be eligible to receive an award of reasonable attorneys' fees and costs incurred in proceedings related to her petition.

The statutory language of the Vaccine Act supports our holding. Section 300aa-15(e)(1) provides for the award of reasonable attorneys' fees and costs arising from "a petition filed under section 300aa-11." As § 300aa-11(a)(1) indicates, "*[a] proceeding for compensation* under the [Vaccine] Program for [a] vaccine-related injury or death *shall be initiated* by service upon the Secretary and *the filing of a petition* . . . ." § 300aa-11(a)(1) (emphasis added). The Court of Federal Claims and its special masters have "jurisdiction *over proceedings* to determine if a petitioner under section 300aa-11 of this title is entitled to compensation under the [Vaccine] Program . . . ." § 300aa-12(a) (emphasis added). In other words, when a petition is filed, it commences a proceeding over which the Court of Federal Claims has jurisdiction. Unless we conclude that Dr. Cloer's filing was a "petition filed," neither we nor

the Court of Federal Claims had jurisdiction over her appeal.[1]

The plain language of the statute indicates that Congress chose not to tie the right to attorneys' fees to compliance with § 300aa-16. Section 300aa-15(e) does not reference § 300aa-16; rather, it refers to "a petition filed under section 300aa-11." Nor does the plain language of § 300aa-11(a)(1) require that a petition be timely filed in accordance with § 300aa-16. By contrast, § 300aa-11(a)(2)(A), which refers to civil actions brought in state or federal court, does require the filing of a petition "in accordance with section 300aa-16."[2] The absence of an analogous reference to § 300aa-16 in the attorneys' fees provision suggests that Congress did not intend to require compliance with § 300aa-16 as a prerequisite for the recovery of attorneys' fees.

Other statutory provisions support this interpretation. Section 300aa-12(b)(1) states that "[i]n all proceedings brought by the filing of a petition under section 300aa-11(b)," the Secretary shall be named as a respondent and shall participate and be represented in the proceedings. Section 300aa-12(b)(2) requires that within 30 days after receiving service of "any petition filed under section 300aa-11," the Secretary shall publish notice of the petition in the Federal Register. Section

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[1] This interpretation is also consistent with Vaccine Rule 2, which states that "[a] proceeding for compensation under the Vaccine Act is commenced by filing a petition" but does not explicitly require that the petition be filed in compliance with § 300aa-16.

[2] Section 300aa-11(a)(2)(A) provides: "No person may bring a civil action for damages . . . in a State or Federal court for damages arising from a vaccine-related injury or death . . . unless a petition has been filed, in accordance with section 300aa-16 of this title . . . ."

300aa-12(c)(6)(E) obligates the Chief Special Master to report to Congress the number of "petitions filed under section 300aa-11" annually. Section 300aa-13(c) defines "record" as the record established on "a petition filed under section 300aa-11." In referring to "petition[s] filed under section 300aa-11," these provisions refer to all petitions, not just those later determined to have been timely filed. Any requirement that naming the Secretary as a party, publishing notice in the Federal Register, reporting to Congress, and creating the record be held at abeyance until a determination is made as to the timeliness of the petition is unreasonable and would have impractical implications.

Section 300aa-15(e) applies to costs "incurred in any proceeding on such petition," and not solely those fully adjudicated on the merits. Congress made clear that denying interim attorneys' fees under the Vaccine Act is contrary to an underlying purpose of the Vaccine Act. *See Avera v. Sec'y of Health & Human Servs.*, 515 F.3d 1343, 1352 (Fed. Cir. 2008). As we explained in *Avera*:

> [O]ne of the underlying purposes of the Vaccine Act was to ensure that vaccine injury claimants have readily available a competent bar to prosecute their claims. *Denying interim fee awards would clearly make it more difficult for claimants to secure competent counsel because delaying payments decreases the effective value of awards* . . . . Interim fees are particularly appropriate in cases where proceedings are protracted and costly experts must be retained.

Id. (emphasis added) (citation omitted); *see also* H.R. Rep. No. 99-908, at 22 (1986) ("the Committee does not intend . . . to limit petitioners' ability to obtain qualified assistance and intends . . . that the court ex-

ercise its discretion to award fees [resulting from] non-prevailing, good faith claims.").

The overarching purpose of the Vaccine Act and the National Childhood Vaccine Injury Compensation Program it created is to award compensation "to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, at 3. Remedial legislation like the Vaccine Act should be construed in a manner that effectuates its underlying spirit and purpose. *See Atchison, Topeka, & Santa Fe Ry. Co. v. Buell*, 480 U.S. 557, 561-62 (1987). Our interpretation of the statute fulfills congressional intent and the Act's legislative purpose. Congress acknowledged that "[l]awsuits and settlement negotiations can take months and even years to complete. Transaction costs—including attorneys' fees and court payments—are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met." H.R. Rep. No. 99-908, at 6. Congress recognized that having to shoulder attorneys' fees could deter victims of vaccine-related injuries from seeking redress.

Congress did not intend for only prevailing petitioners to receive an award of reasonable attorneys' fees and costs. To the contrary, compensation on a petition should include "an amount to provide for reasonable attorneys' fees and other costs incurred in *proceedings on the petition*. But even where the court does not award compensation on a petition, it may, in its discretion, make such an award for attorneys' fees and costs if it determines that the *action* was brought in good faith and that there was a reasonable basis for the claim for which the action was brought." *Id.* at 21 (emphasis added).

The statutory language requiring a reasonable basis for the claim for which the petition was brought is broad enough to encompass the statute of limitations issue as well as the underlying merits of the claim. It is beyond dispute that Congress intended attorneys' fees to be awarded only in cases brought in good faith and where there was a reasonable basis for the claim underlying the petition, even where the petitioner does not prevail. The good faith and reasonable basis requirements apply to the claim for which the petition was brought; this applies to the entire claim, including timeliness issues. Attorneys' fees should be denied if on remand, it is determined that the petition was not brought in good faith or there was no reasonable basis for the claim for which the petition was brought.

Finally, Dr. Cloer deserves a determination as to whether she is eligible to receive attorneys' fees because her appeal inspired a shift in vaccine jurisprudence. Indeed, the government does not dispute the reasonableness of Dr. Cloer's underlying claim or allege that it was not brought in good faith, which is generally presumed. The confines of the Vaccine Act make clear that a petitioner need not prevail to receive attorneys' fees.

The dissent contends that Dr. Cloer is not entitled to attorneys' fees as a matter of law and creates a rigid rule applicable to requests for attorneys' fees in vaccine cases where the petitioner's claim is rejected solely on limitations grounds. *Cloer* overruled our precedent treating the statute of limitations as jurisdictional and did not endorse the underlying statutory interpretation of such cases. Rather, it eliminated the entire bases for such opinions. Despite this, the dissent would treat Dr. Cloer's petition under a pre-*Cloer* analysis by retroac-

tively eliminating jurisdiction to award attorneys' fees in connection with an unsuccessful statute of limitations argument.

The dissent, primarily in footnote one, argues that § 12 vests the Court of Federal Claims and special masters with jurisdiction to determine whether a petitioner is eligible to file a petition, even if the petition is later deemed untimely. *See* Dis. Op. at 2 n.1. This construction of "petition filed" for purposes of § 300aa-15(e) is inconsistent with the language of the Vaccine Act. Because § 300aa-16(a) states that "no petition may be filed" if it is untimely, the dissent creates a distinction between a "filing a petition" for purposes of § 300aa-11 and a "petition filed" for purposes of § 300aa-15(e) and other statutory provisions. Under this reasoning, an untimely filed petition is a "petition" sufficient to commence proceedings but is not a "petition filed" for purposes of § 300aa-16 and § 300aa-12. Such a distinction between "petitions" and "petitions filed" leads to absurd results, namely that neither this court nor the Court of Federal Claims had jurisdiction over Dr. Cloer's petition.

The dissent also contends that Dr. Cloer is not entitled to attorneys' fees because the Vaccine Act requires an evaluation of the reasonableness of the claim for which the petition was brought, which indicates that Congress did not contemplate awarding attorneys' fees in a case that never reached a merits determination. *See* Dis. Op. at 4. However, as explained above, § 300aa-15(e) explicitly refers to fees "incurred in any proceeding on such petition," including non-frivolous petitions ultimately unsuccessful on limitations grounds. Holding that attorneys' fees are only available where a petition has been subjected to a final adjudication on the merits

is also inconsistent with the recognized practice of awarding interim attorneys' fees, which by definition does not require a final adjudication on the merits.

The dissent claims that "the legislative history of the Vaccine Act is silent as to the reason for the Act's highly unusual attorney fee provision" and goes on to speculate on Congress's motivation for departing from the typical American Rule of fee awards. *See* Dis. Op. at 5 ("It may well be that Congress concluded . . ."); *id.* ("Congress could well have concluded . . ."). Such speculation is unnecessary, however, in light of the remedial nature of the Vaccine Act and Congress's intent to facilitate awards to injured parties.

The dissent advocates adoption of a strict rule that strips discretion from the court and in so doing disregards the Vaccine Act's spirit and purpose. The dissent's interpretation would discourage potential Vaccine Act petitioners from pursuing claims and ignores that potential petitioners will likely be reluctant to bring claims under the Vaccine Act for fear of significant financial risk even when strong arguments exist to challenge the applicability of the statute of limitations.

III. Conclusion

This Order recognizes that issues relating to the award of attorneys' fees in connection with challenges brought on limitations grounds will frequently arise in vaccine injury cases. Under *Cloer*, the Vaccine Act does not incorporate a discovery rule, and the statute of limitations begins to run on "the calendar date of the occurrence of the first medically recognized symptom or manifestation of onset of the [claimed] injury," subject to the doctrine of equitable tolling. *Cloer*, 654 F.3d at 1325, 1340, 1344-45. If a discovery rule were adopted, as Dr.

Cloer now urges in the Supreme Court, the limitations inquiry in vaccine injury cases would then become when the claimant first discovered or should have discovered the potential cause of the disease or injury, rather than when the claimant first experienced symptoms.[3] Under either view, a petitioner may become embroiled in litigation regarding the statute of limitations, and today's order will enable reasonable claims for attorneys' fees arising from that litigation.

A petitioner who asserts an unsuccessful but non-frivolous limitations claim should be eligible for a determination of whether reasonable attorneys' fees and costs incurred in proceedings related to his or her petition should be awarded. Therefore, we remand for a determination as to whether Dr. Cloer's petition was brought in good faith and whether the claim for which her petition was brought had a reasonable basis.

Accordingly,

IT IS ORDERED THAT:

Dr. Cloer's application for reasonable attorneys' fees and costs be remanded to the Court of Federal Claims. The Court of Federal Claims is directed to make a determination consistent with this Order.

FOR THE COURT

Apr. 11, 2012
Date

/s/ JAN HORBALY
JAN HORBALY
Clerk

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[3] Dr. Cloer filed a petition for certiorari in the United States Supreme Court on December 29, 2011.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

Appeal from the United States Court of Federal Claims in 05-VV-1002, Judge Lawrence J. Block

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BRYSON, *Circuit Judge*, with whom RADER, *Chief Judge*, and LOURIE, CLEVENGER, GAJARSA, and PROST, *Circuit Judges*, join, dissenting.

The question whether a party who has filed an untimely Vaccine Act petition is entitled to an award of attorneys' fees under section 15(e)(1) of the Act, 42 U.S.C. § 300aa-15(e)(1), presents a difficult statutory construction issue. While there is no clear path to the answer in the plain language or legislative history of the Vaccine Act, I believe that close attention to the text that Congress chose and consideration of the role of the fee-shifting provision both in the Vaccine Act and in the broader context of federal fee-shifting statutes require that we deny the fee request in this case.

1. In *Brice v. Secretary of Health & Human Services*, 358 F.3d 865, 869 (Fed. Cir. 2004), this court held that the attorneys' fees provision of the Vaccine Act

makes fees available only "in connection with a petition filed under section 300aa-11," and that a petition dismissed on grounds of untimeliness is not "a petition filed under section 300aa-11," as required by section 15(e). Similarly, in *Martin v. Secretary of Health & Human Services*, 62 F.3d 1403, 1406 (Fed. Cir. 1995), the court explained that in order for an attorneys' fee award to be permitted under section 15(e)(1), "there must first be a judgment 'on such a petition'—that is, 'on a petition filed under section 300aa-11.'" While this court's en banc decision in *Cloer v. Secretary of Health & Human Services*, 654 F.3d 1322 (Fed. Cir. 2011), overruled *Brice* and *Martin* insofar as they were based on lack of subject matter jurisdiction, *see* 654 F.3d at 1341 & n.9, the en banc court did not disavow the analysis of the statutory structure in those cases, and that analysis is still sound. In substance, as modified by the en banc decision in *Cloer*, *Brice* and *Martin* stand for the following principles: (1) section 16(a) of the Vaccine Act directs that "no petition may be filed for compensation under the Program"—and thus under section 11—after the expiration of the applicable time period, 42 U.S.C. § 300aa-16(a); (2) section 15(e)(1) allows an attorneys' fee award only when a petition is filed under section 11, *id.* § 300aa-15(e)(1); and therefore (3) an attorneys' fee award may be made only if the claimant files a timely petition, either by satisfying the applicable limitations period of section 16 or successfully invoking equitable tolling.[1]

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[1] This interpretation of the statute does not, as the majority opinion suggests, create a jurisdictional impasse. Section 12 of the Act gives the Court of Federal Claims and the special masters jurisdiction "over proceedings to determine if a petitioner under section 300aa-11 of this title is entitled to compensation." 42 U.S.C. § 300aa-12(a). That refer-

Besides the reference to a petition filed under section 11, section 15(e)(1) provides for an award of attorneys' fees to an unsuccessful petitioner "if the judgment . . . on such a petition does not award compensation." Although that language, standing alone, could be understood to refer either to a judgment on the merits or to a dismissal for untimeliness, the statutory context indicates that it does not refer to a judgment dismissing the petition for untimeliness. The same language is used in section 21 of the statute, where it clearly refers only to a judgment on the merits. That section provides that if "the judgment did not award compensation," the petitioner is required to file "an election in writing to accept the judgment or to file a civil action for damages for such injury or death." 42 U.S.C. § 300aa-21(a)(2). Because the timely filing of a Vaccine Act petition is a prerequisite to filing a civil tort suit, *see id.* § 300aa-11(a)(2)(A), a claimant who has filed an untimely petition is not eligible to file a civil action for damages. The requirement in section 21 that a petitioner elect whether to file a civil tort suit when "the judgment did not award compensation" therefore does not refer to a claimant whose petition has been denied as untimely. In light of the meaning given to that phrase in section 21, it is fair to infer that the parallel reference in section 15(e)(1) to a "judgment [that] does not award compensa-

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ence gives the Court of Federal Claims and the special masters jurisdiction to determine whether or not the petitioner is eligible under section 16 to file a petition for compensation, even if the petitioner is ultimately determined not to be eligible to file a petition. *See Martin*, 62 F.3d at 1406.

tion" likewise denotes a judgment on the merits, not a dismissal.[2]

Finally, section 16(c) of the Act reinforces the view that the phrase "a petition filed under section 300aa-11" in section 15(e) refers to a timely petition. Section 16(c) provides that if a petition is filed under section 11, state statutes of limitations shall be stayed for any civil action brought for the vaccine-related injury, beginning on the date the petition is filed and ending on the date that an election is made under section 21 to file the civil action. 42 U.S.C. § 300aa-16(c). Because, as noted, such a civil action cannot be filed if the petition was untimely, the reference to "a petition filed under section 300aa-11" in section 16(c) can only mean a petition filed, as section 11 requires, in accordance with section 16, i.e., within the statutory time limits. The same language—"a petition filed under section 300aa-11"—is used as a prerequisite for the payment of attorneys' fees and costs in section 15(e), which is a further textual indication that attorneys' fees and costs are not intended to be paid in cases in which the petition was untimely.

2. Although the legislative history of the Vaccine Act is silent as to the reason for the Act's highly unusual

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[2] The majority finds support for its decision in *Avera v. Secretary of Health & Human Services*, 515 F.3d 1343 (Fed. Cir. 2008), which held that the Vaccine Act permits an award of interim fees to petitioners who are seeking compensation. *Avera*, however, concerned an interim award for a petitioner who had filed a timely petition and therefore was in position to obtain a judgment on the merits, either awarding or denying compensation. Nothing in *Avera* suggests that a fee award, whether interim or otherwise, is appropriate for a claimant who has not filed a timely petition. And nothing in this opinion would prohibit granting interim fees to a petitioner who has filed a timely petition and is seeking a compensation award.

attorney fee provision, the requirement that there be a timely filed petition and a judgment on the merits of the compensation request, as opposed to a dismissal of the petition for untimeliness, makes sense in light of the development and purposes of the Act.

The Vaccine Act evolved from a series of bills that were introduced over a three-year period. All of the bills that featured compensation proceedings contained attorney fee provisions, and all of them, until the very end of the legislative process, required the claimant to be a prevailing party in order to be eligible for a fee award. *See* S. 2117 (Nov. 17, 1983); H.R. 5810 (June 7, 1984); H.R. 1780 (Mar. 27, 1985); S. 827 (Apr. 2, 1985). Several of the early proposals would have allowed claimants to elect to proceed either through the compensation program or by way of a civil tort remedy. The bill that was ultimately enacted, however, required that claimants exhaust their remedies through the Vaccine Act compensation program before filing a tort action. H.R. 5546 (Sept. 18, 1986) (incorporated into S. 1744, which became P.L. 99-660, Title III of which is the Vaccine Act). The proposed exhaustion requirement was controversial and sparked strong opposition from those who did not wish to see any impediments placed in the way of plaintiffs' ability to pursue traditional civil tort remedies. *See Vaccine Injury Compensation: Hearing on H.R. 1780, H.R. 4777, and H.R. 5184 Before the H. Subcomm. on Health and the Env't of the H. Comm. on Energy and Commerce*, 187, 191, 216 (1986) (statements of Jeffrey H. Schwartz, President, Dissatisfied Parents together).

It may well be that Congress concluded that because it was imposing an additional burden on claimants, it

should make fee awards available to claimants who were required to go through the compensation program even though they were not eager to participate in the program and did not ultimately receive compensation. But since claimants who file untimely petitions do not enter the Vaccine Act compensation program and thus do not face the burden of litigating their entitlement to compensation on the merits, Congress could well have concluded that it did not make sense to provide attorneys' fees to those parties in connection with their unsuccessful efforts to avoid the limitations period and gain access to the program.

3. In attempting to discern Congress's purpose in drafting the attorney fee provision at issue in this case, it is important to keep in mind some general principles governing fee-shifting statutes. The background rule applied by American courts is the "American rule," under which each party pays its own fees. *See Alyeska Pipeline Serv. Co. v. Wilderness Soc'y*, 421 U.S. 240, 245 (1975). Some statutes permit or direct a departure from that rule, allowing prevailing parties to obtain an award of attorneys' fees from the losing party under certain circumstances. But it is almost unknown in American practice for a statute to provide that the prevailing party will pay the losing party's attorneys' fees. The Supreme Court put that point succinctly in *Ruckelshaus v. Sierra Club*, 463 U.S. 680, 683-84 (1983), where it noted (emphasis in original):

> Our basic point of reference is the "American Rule," *see Alyeska Pipeline Co. v. Wilderness Society*, 421 U.S. 240, 247 (1975), under which even "the *prevailing* litigant is ordinarily not entitled to collect a reasonable attorneys' fee from the *loser*." It is clear

> that generations of American judges, lawyers, and legislators, with this rule as the point of departure would regard it as "quite inappropriate" to award the "loser" an attorney's fee from the "prevailing litigant."

The Supreme Court in *Ruckelshaus* was able to identify only one federal statute that, as of that time, permitted fee awards to a party whose views were rejected. That statute applied not to litigation, but to the promulgation of rules regarding the regulation of hazardous chemical substances. *Ruckelshaus*, 463 U.S. at 685 n.7, citing 15 U.S.C. § 2605(c)(4)(A).

The statute at issue in this case plainly allows losing parties to obtain a fee award from the prevailing party in some circumstances. But because Congress departed from the governing principles applied in virtually every other federal fee-shifting statute, we should be cautious in interpreting the statutory mandate to extend beyond those cases in which fee-shifting was clearly intended. *See Robert C. Herd & Co. v. Krawill Mach. Corp.*, 359 U.S. 297, 304-05 (1959) (a rule of law "in derogation of the common law . . . must be strictly construed"); *In re Crescent City Estates*, 588 F.3d 822, 826 (4th Cir. 2009) ("Because fee-shifting statutes are 'in derogation of the common law,' courts are obligated to construe them strictly.").

That is particularly true in light of the practical effect of requiring the government to pay attorneys' fees to persons who both fail to file a timely petition and then fail in their effort to show that their untimeliness was excused by equitable tolling—which is the only class of persons potentially affected by the resolution of the fee issue before us. Section 15(e)(1) of the Vaccine Act pro-

vides that attorneys' fees can be paid to a petitioner to whom the court does not award compensation "if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought." 42 U.S.C. § 300aa-15(e)(1). As a preliminary matter, it would seem that if Congress had contemplated that claimants making untimely filings should be eligible for attorneys' fees, it would have required both a reasonable basis for the underlying claim and a reasonable basis for the equitable tolling argument; it seems unlikely that Congress would want to compensate claimants who had a reasonable basis for the underlying claim but no reasonable basis to qualify for equitable tolling. More fundamentally, it seems quite implausible that in a case in which the claimant's submission was held to be untimely, Congress would have wanted the special master and the court to conduct a collateral proceeding to determine whether, had the claim been eligible for consideration, it would have had a reasonable chance of success. Yet that is the effect of the court's ruling today.

In a case that has gone to judgment on the merits and the petitioner has lost, it is fairly easy for the special master and the court to determine whether the petitioner's position on the merits was reasonable. In that setting, the special master and the court will have the entire record of the case before them to enable them to make that determination. It is an entirely different matter for the special master to have to conduct a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding. Quite apart from the burden on the special masters and the court, the amount of attorney time (and thus the accumulating fees) that

would be consumed by such a proceeding would likely exceed the fees expended on the typically much simpler question whether equitable tolling is available to the claimant. Again, it seems unlikely that Congress envisioned such a scheme, and in the absence of express congressional authorization, we should be cautious about engrafting one onto the statute. Caution is especially warranted in a case authorizing a monetary award against the government in light of well-settled principles of sovereign immunity. The Supreme Court has held that "[e]xcept to the extent it has waived its immunity, the Government is immune from claims for attorney's fees." *Ruckelshaus*, 463 U.S. at 685-86. And the Court has recently reaffirmed that "a waiver of sovereign immunity must be 'unequivocally expressed' in statutory text"; that "[a]ny ambiguities in the statutory language are to be construed in favor of immunity"; and that "[a]mbiguity exists if there is a plausible interpretation of the statute that would not authorize money damages against the government." *FAA v. Cooper*, No. 10-1024 (U.S. Mar. 28, 2012), slip op. 5.

For these reasons, I respectfully dissent.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

Decided: Aug. 5, 2011

Appeal from the United States Court of Federal Claims in 05-VV-1002, Judge Lawrence J. Block

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Before: RADER, *Chief Judge*, NEWMAN, LOURIE, CLEVENGER, BRYSON, GAJARSA,* LINN, DYK, PROST, MOORE, O'MALLEY, and REYNA, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* CLEVENGER, in which *Chief Judge* RADAR, and *Circuit Judges* LOURIE, BRYSON, GAJARSA, PROST, MOORE, and O'MALLEY join.

CLEVENGER, *Circuit Judge*.

This case involves the interpretation and application of the statute of limitations in the National Childhood

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* Judge Gajarsa assumed senior status on July 31, 2011.

Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act"). The statute of limitations provides that if a vaccine-related injury occurred as a result of the administration of a vaccine, "no petition may be filed for compensation under the Program for [a vaccine-related] injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such [vaccine-related] injury." 42 U.S.C. § 300aa-16(a)(2).

Dr. Melissa Cloer received three Hepatitis-B ("Hep-B") vaccinations in 1996 and 1997. Years later, in 2005, Dr. Cloer filed a claim under the National Vaccine Injury Compensation Program ("Vaccine Program"), established by the Vaccine Act, seeking compensation for a multiple sclerosis ("MS") injury she alleged was caused by the administration of the vaccine. The Chief Special Master and Court of Federal Claims dismissed Dr. Cloer's claim as untimely because it was filed more then 36 months after her first symptom of MS occurred in 1997. *Cloer v. Sec'y of Health & Human Servs.*, 85 Fed. Cl. 141 (2008). Dr. Cloer appealed the decision and a panel of this court reversed, ruling in her favor. *Cloer v. Sec'y of Health & Human Servs.*, 603 F.3d 1341 (Fed. Cir. 2010), *vacated*, 399 Fed. App'x 577 (Fed. Cir. Oct 25, 2010). Subsequently, we granted the petition of respondent and appellee Secretary of Health and Human Services ("the government") to rehear the case en banc, vacated the panel opinion, *Cloer*, 399 Fed. App'x at 577, and requested additional briefs from the parties.

Consistent with the plain meaning of the statute, we hold that the statute of limitations of the Vaccine Act begins to run on the calendar date of the occurrence of the first medically recognized symptom or manifestation

of onset of the injury claimed by the petitioner. Because Dr. Cloer's first symptom of MS, recognized as such at the time she suffered the symptom, occurred more than 36 months before the filing of her petition for compensation, her claim is time-barred. We today also reverse our previous holding in *Brice v. Secretary of Health & Human Services*, 240 F.3d 1367 (Fed. Cir. 2001) ("*Brice*"), which precluded application of the doctrine of equitable tolling in Vaccine Act cases, but reject the ground upon which Dr. Cloer seeks the benefit of equitable tolling in this case. We thus affirm the judgment of the Court of Federal Claims dismissing Dr. Cloer's claim as untimely.

In Part I below, we briefly address the background against which Congress enacted the Vaccine Act and in particular the statute of limitations chosen by Congress. Part II sets forth the essential facts of the case. In Part III, we discuss the proceedings before the Chief Special Master and the Court of Federal Claims. Part IV states our standard of review. In Part V, we set forth and respond to the three arguments Dr. Cloer presented to the court in her initial briefs and at the initial panel hearing of the case. In Part VI, we address and answer the three specific questions on which we requested additional briefing to the en banc court. Our en banc hearing focused on these questions.

I

In 1986, Congress established the Vaccine Program to provide compensation for vaccine-related injuries and deaths. *See* 42 U.S.C. § 300aa-10. The Vaccine Act creates a "no-fault" Federal program for compensating injuries that are either presumed or proven to be causally connected to vaccines. The Vaccine Act arose be-

cause "the Nation's efforts to protect its children by preventing disease have been [] a success," but "[w]hile most of the Nation's children enjoy greater benefit from immunization programs, a small but significant number have been gravely injured." H.R. Rep. No. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345. However, "at least in part as a result of [the] increase in litigation, the prices of vaccines [] jumped enormously." *Id.* Congress created the Vaccine Program to balance these two primary concerns that the tort system was failing to adequately compensate persons injured from vaccinations that were undergone for the public good and that excessive tort liability was unsustainably raising prices and discouraging vaccine manufacturers from remaining in the market. *See id.* at 3-7, *reprinted in* 1986 U.S.C.C.A.N. at 6344-48.

Congress noted "for the relatively few who are injured by vaccines—through no fault of their own—the opportunities for redress and restitution [were] limited, time-consuming, expensive, and often unanswered." *Id.* at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347. In response, Congress created the Vaccine Program to be "simple, and easy to administer" while also being "expeditious and fair." *Id.* at 7, 12, *reprinted in* 1986 U.S.C.C.A.N. at 6348, 6353. To compensate injured persons quickly and fairly, the Vaccine Act exempted petitioners from the tort requirements of demonstrating that a manufacturer was negligent or that a vaccine was defective. *Id.* at 12-13, *reprinted in* 1986 U.S.C.C.A.N. at 6353-54. For some injuries which the medical profession at large recognized as especially likely to be caused by vaccine administration, Congress exempted petitioners from the burden of proving causation. *Id.* In sum, while the Vaccine Act does not prohibit a petitioner from

going to state court after completion or unfair delay of the compensation proceedings, the Vaccine Program was intended to "lessen the number of lawsuits against manufacturers" and "provide[] relative certainty and generosity" of compensation awards in order to satisfy petitioners in a fair, expeditious, and generous manner.[1] *Id.*

The legislative history shows that Congress considered alternative statutes of limitation for claims filed in the Vaccine Program. The House of Representatives version, H.R. 1780, introduced on March 27, 1985, provided that "any claim under this title that is filed more than two years after the first manifestation of a vaccine-related injury shall be barred." National Childhood Vaccine-Injury Compensation Act of 1985, H.R. 1780, 99th Congress § 2112(a) (1985). A subsequent Senate bill, S. 827, introduced on April 2, 1985, took a different approach. Unlike H.R. 1780, S. 827 did not trigger the statute of limitations upon the occurrence of the first manifestation of an injury. Instead, it provided that actions for compensation "shall be barred if the petitioner fails to file the action . . . within 5 years after the occurrence of the compensable complication or residual effect of the illness, disability [or] injury." National Childhood Vaccine Injury Compensation Act of 1985, S. 827, 99th Congress § 2106(a) (1985). In addition, the 5 year statute did not apply at all if a petitioner could demonstrate that she either (a) did not receive the parent information about vaccines required under the bill, or (b) did not know the complication or effect of her injury was compensable under the program. *Id.*

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[1] The Supreme Court has held that the Vaccine Act preempts state law vaccine design defect claims. *See Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1075 (Feb. 22, 2011).

§ 2106(b). S. 827 set forth a Vaccine Table, listing specific vaccines, specific injuries, and specific time periods for the first symptom or manifestation of onset of a listed injury after administration of a vaccine. Compensation was required if a petitioner could meet the specified time periods for a listed vaccine and injury. But if a petitioner could not meet the time period requirements, the petitioner could still prevail if "the petitioner demonstrates on the basis of credible evidence" that the injury "suffered by petitioner was caused by a vaccine listed in the Vaccine Injury Table." *Id.* § 2105(a)(2). The Senate bill thus incorporated both strict liability and causation in fact liability.

Ultimately, Congress settled on the former of the two approaches. H.R. 5546 (September 18, 1986) followed the approach of H.R. 1780, and provided that if a vaccine-related injury occurred as a result of the administration of a vaccine listed on the Vaccine Injury Table, "no petition may be filed for compensation under the Program after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury." National Childhood Vaccine Injury Act of 1986, H.R. 5546, 99th Congress § 2116(a)(1)(B) (1986). Both the House and Senate passed H.R. 5546, as incorporated into S. 1744, and the statute of limitations was signed into law on November 14, 1986 as part of the National Childhood Vaccine Injury Act of 1986. Pub. L. No. 99-660, 100 Stat. 3743 (1986).

The legislative record is thus clear that Congress chose to trigger the statute of limitations from the date of the occurrence of the first symptom or manifestation of onset of an injury, not from the date of the injury it-

self. Further, Congress was alerted to the consequences of its choice. For example, at a July 18, 1985 Senate Hearing before the Committee on Labor and Human Resources, the president of Dissatisfied Parents Together ("DPT") submitted testimony comparing the different pending House and Senate bills. *See To amend the Public Health Service Act to provide for the compensation of children and others who have sustained vaccine-related injuries, and for other purposes: Hearing on S. 827 before the S. Comm. on Labor and Human Res.*, 99th Cong. 41 (1985) (statement of Jeffrey H. Schwartz, President of DPT). The testimony noted that under the Senate proposal, S. 827, a claim "must be filed within five years of occurrence of injury" but "[t]his limitation does not apply if claimant did not receive the required parent information packet or did not know the injury was compensable." *Id.* at 56. The testimony sharply contrasted this with the pending House proposal, H.R. 1780, under which a claim "must be filed within 2 years after first manifestation of injury" and "[t]his limit applies regardless of when claimant discovered the causal link between the injury and the vaccine." *Id.*

From the above, we note that the Vaccine Act, as enacted, reflects a specific decision by Congress that the Act's statute of limitations would begin to run not on the date of injury (as is sometimes seen in other contexts), but on the date that injury first became symptomatic or manifested.

II

The essential facts of this case are undisputed. Petitioner Melissa Cloer is a physician with MS.[2] Prior to receiving her Hep-B immunizations in 1996 and 1997, Dr. Cloer had no significant medical issues and enjoyed generally good health. Dr. Cloer received her first two doses of Hep-B vaccine without major incident and received her third and final vaccination on April 3, 1997. Approximately one month thereafter she began to experience numbness in her left forearm and hand. She also began to experience what she described as an "electric shock sensation" with "electric like sensations going down the center of her back to both feet with forward head flexion." This sensation is known as Lhermitte sign, long recognized by the medical profession as a common symptom of MS. *See Dorland's Illustrated Medical Dictionary* 1700 (30th ed. 2003) (defining Lhermitte sign as the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in multiple sclerosis but also in compression and other disorders of the cervical cord).

In 1998, about a year after her final vaccination, Dr. Cloer sought treatment from Dr. Michael Andrew

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[2] MS is "a disease in which there are foci of demyelination of various sizes throughout the white matter of the central nervous system, sometimes extending into the gray matter. Typically, the symptoms of lesions of the white matter are weakness, incoordination, parenthesis, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that the term *multiple* also refers to remissions and relapses that occur over a period of many years." *Borrero v. Sec'y of the Dep't of Health & Human Servs.*, No. 01-417V, 2008 WL 4527837 at *1 n.4 (Fed. Cl. Sp. Mstr. Sept. 24, 2008) (quoting *Dorland's Illustrated Medical Dictionary* (30th ed. 2003) at 1669).

Meyer, an expert in the field of neurology with a specialty in MS. After an MRI examination, Dr. Meyer noted "probable early inactive non-progressive CNS [central nervous system] demyelination/MS," although he explained that her situation did not meet "formal diagnostic criteria for clinically definite MS." *Cloer*, 85 Fed. Cl. at 144. Even so, because the MRI revealed lesions on the white matter of her central nervous system, Dr. Meyer concluded that Dr. Cloer could have MS, Singular Sclerosis, Lyme Disease, and/or acute disseminating encephalomyelitis, along with other demyelinating processes. *Id.* at 143. Before the Chief Special Master, Dr. Meyer testified that Dr. Cloer suffered from MS in 1998 because "the first MS related symptom was the [Lhermitte's] phenomenon that she had in 1997." *Cloer v. Sec'y of the Dep't of Health & Human Servs.*, No. 05-1002V, 2008 WL 2275574, at *6 (Fed. Cl. Sp. Mstr. 2008) ("*Special Master Opinion*"), *aff'd*, 85 Fed. Cl. 141 (2008).

On May 6, 1999, Dr. Cloer received a neurological examination from Dr. Ted Colapinto. *Cloer*, 85 Fed. Cl. at 144. Dr. Colapinto noted Dr. Cloer's medical history and recorded her complaints of numbness in her face, arms and legs, and her difficulty in walking. *Id.* He concluded that Dr. Cloer's symptoms likely represented a demyelinating disease, commenting that "[Dr. Cloer] is having waxing and waning neurological symptoms in multiple areas of her body. I fear that this may likely represent demyelinating disease." *Sp. Mstr. Op.*, 2008 WL 2275574 at *6. Dr. Cloer continued to suffer from numerous, but somewhat fleeting, symptoms. In May 2004, Dr. Cloer applied for and was awarded monthly Social Security disability benefits. Dr. James P. Metcalf conducted a comprehensive medical examination at the

time and noted that appellant "first beg[a]n to have some symptoms consistent with MS in 1997," although her "symptoms waxed and waned until the fall of 2003 when she beg[a]n to have manifestations of the full blown disease." *Id.* at *2.

Dr. Cloer claims that even in 2003 upon receiving a diagnosis of MS she remained unaware of any causal association between the Hep-B vaccine and MS. Dr. Cloer testified that she first became aware of the possible link when she read an editorial and prospective French study in the September 2004 issue of *Neurology*. Cloer Aff., J. App'x 270-71; *see also* Robert T. Naismith, M.D. & Anne H. Cross, M.D., *Does the hepatitis B vaccine cause multiple sclerosis?*, 63 Neurology 772 (Sept. 2004); and Miguel A. Hernán, M.D. et al., *Recombinant hepatitis B vaccine and the risk of multiple sclerosis*, 63 Neurology 838 (Sept. 2004). On October 11, 2004, Dr. Cloer reported to the Vaccine Adverse Event Reporting System that she had experienced numbness and tingling after her first two Hep-B vaccinations, followed by "Lhermitte's" approximately one month after her third vaccination. *Sp. Mstr. Op.*, 2008 WL 2275574 at *1-2. Dr. Cloer subsequently filed her petition for compensation for a vaccine injury on September 16, 2005. *Cloer*, 85 Fed. Cl. at 144.

III

Before the Chief Special Master, Dr. Cloer did not challenge the evidence that she had suffered symptoms of MS, and likely the manifestation of onset of MS, more than three years before the filing of her petition, thus time-barring her petition. Instead, Dr. Cloer's primary argument to the Chief Special Master was that the statute of limitations did not begin to run against her until

after receipt of a "clinically definite" diagnosis of MS. Dr. Meyer, Dr. Cloer's treating physician, explained that because Dr. Cloer's symptoms did not amount to a clinically definite diagnosis of MS until November 2003, Dr. Cloer was unaware of her injury until this time, and thus also could not have been aware that the Hep-B vaccine caused her injury. Since Dr. Cloer's petition was filed in September 2005, she argued it was filed within the 3 year statute of limitations of when she was first diagnosed with MS. Essentially, Dr. Cloer asked the Chief Special Master to read the phrase "symptom or manifestation of onset" as only triggering upon a symptom or manifestation that is clinically diagnosed as the disease itself.

Relying on precedent of this court, the Chief Special Master rejected Dr. Cloer's theory and held that the statute of limitations begins to run on the occurrence of the first symptom or manifestation of onset of the injury that the petitioner alleges has resulted from the vaccination. The Chief Special Master discussed at length our decision in *Markovich v. Secretary of Health & Human Services*, 477 F.3d 1353 (Fed. Cir. 2007), quoting that "the terms of the Vaccine Act demonstrate that Congress intended the limitation period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." *Sp. Mstr. Op.*, 2008 WL 2275574, at *5 (quoting *Markovich*, 477 F.3d at 1358). The Chief Special Master expressly dismissed Dr. Cloer's argument that a "clinically definite"diagnosis is required by *Markovich*:

> Petitioner misreads *Markovich*. The Court's holding was that for purposes of § 300aa-16(a)(2), "the first

> symptom or manifestation of onset" is the "first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." *Markovich*, 477 F.3d at 1360. There is no requirement that the *vaccine injury* be diagnosed.

Id. at *9.

Just as she did before the Chief Special Master, Dr. Cloer focused her argument at the Court of Federal Claims on her failure to receive a "clinically definite" diagnosis of MS until 2003, elaborating that "because the first set of symptoms may be premature for a definitive diagnosis of a disease, it cannot itself constitute a 'vaccine injury.'" She also pointed to 42 U.S.C. § 300aa-11(c)(1)(D)(i), which contains a petition content requirement stating that "a petition for compensation . . . for a vaccine-related injury . . . shall contain . . . an affidavit, and supporting documentation, demonstrating that the person . . . suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after administration of the vaccine. . . . " Because of this requirement, she argued that the statute of limitations does not begin to run until a petitioner has suffered the residual effects or complications for more than 6 months after administration of the vaccine. She alleged as a matter of fact that she did not meet this requirement until late in 2003, which if true, would bring her 2005 petition within the statute of limitations. Finally, she asked for relief by way of equitable tolling, notwithstanding our opinion in *Brice* that equitable tolling is not available under the Vaccine Act. She sought relief under equitable tolling because she was not diagnosed with MS until 2003 and there was no reason for her to suspect a vaccine link to

MS until 2004. *Cloer*, 85 Fed. Cl. at 145, 149.

The Court of Federal Claims rejected Dr. Cloer's arguments. The court understood Dr. Cloer's primary argument to be that a "vaccine-related" injury could not occur based on the first occurrence of a symptom of the injury, but instead would arise from "a 'physician's ultimate diagnosis" that the "vaccine caused the complained-of specific injury." *Id.* at 149. The court held her argument "contrary to *Markovich*, which held that the limitations period begins to run at the first occurrence of a symptom even though an exact diagnosis may be impossible until some future date when more symptoms or medical data are forthcoming." *Id.* Referring to the trigger for the statute of limitations, the court quoted from *Markovich*: "Congress intended the limitations period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." *Id.* (quoting *Markovich*, 477 F.3d at 1358). The court also relied on the observation in *Brice* that the statute begins to run "upon the first symptom or manifestation of the onset of injury, even if the petitioner would not have known at that time that the vaccine had caused an injury." *Brice*, 240 F.3d at 1373.

The court held that the Lhermitte sign in 1997 was the first symptom of Dr. Cloer's MS and triggered the statute of limitations, *Cloer*, 85 Fed. Cl. at 147-49, which the court held is unaffected by the 6 month requirement in 42 U.S.C. § 300aa-11(c)(1)(D)(i). The court found Dr. Cloer's petition is time barred and affirmed the Chief Special Master. The court also noted that *Brice* bars Dr. Cloer's request for relief by way of equitable tolling

of the statute of limitations. *Id.* at 149, 152.

IV

We review the Special Master's decision under the same arbitrary and capricious standard as did the Court of Federal Claims. 42 U.S.C. § 300a-129(e)(2)(B); *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). We owe no deference on questions of law, *Whitecotton ex rel. Whitecotton v. Sec'y of Health & Human Servs.*, 81 F.3d 1099, 1106 (Fed. Cir. 1996), but review factual findings for clear error, *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1523 (Fed. Cir. 1991). In this case we are concerned with issues of statutory interpretation: what constitutes a "vaccine-related injury" and what event triggers the running of the Vaccine Act's statute of limitations.

V

In her initial appeal briefs, Dr. Cloer abandons her argument that no vaccine-related injury can occur before a clinically definite diagnosis is made. Instead, she argues that a "vaccine-related injury" for purposes of the Vaccine Act and its statute of limitations cannot occur until the medical community at large understands and recognizes the causal relationship between the claimed injury and the administration of a vaccine. Dr. Cloer alleges that because an injury cannot be alleged as "vaccine-related" until after this recognition, any other interpretation of the statute of limitations would be unfair. Dr. Cloer also argues that the statute of limitations should not trigger until after a petitioner has suffered from six months of consistent, clinically-related symptoms, citing 42 U.S.C. § 300aa-11(c)(1)(D)(i). Otherwise, because a petitioner is required to attest, as a petition

requirement, to residual effects or complications lasting "more than 6 months after the administration of the vaccine," Dr. Cloer argues the statute of limitations would be unfairly reduced to less than 36 months. Finally, Dr. Cloer requests that this court reconsider the holding in *Brice* that equitable tolling is not available under the Vaccine Act.

As noted above, the panel opinion ruled in Dr. Cloer's favor, accepting her argument that the statute of limitations begins to run upon formation of a consensus in the medical community that a vaccine causes the injury claimed. The panel did not reach Dr. Cloer's other arguments. Because the panel opinion is vacated, we respond to her original arguments in subparts A, B, and C below.

A

We first address Dr. Cloer's primary argument on appeal that a "vaccine-related" injury only arises upon a medically established causal link between an injury and the vaccine in question. Our analysis must begin with the plain language of the statute. The Vaccine Act states that "if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset" of injury. 42 U.S.C. § 300aa-16(a)(2). The plain language of the Vaccine Act thus requires injured parties to file Vaccine Program petitions within 36 months of the date of the first symptom or manifestation of onset of the "vaccine-related injury."

The Act defines "vaccine-related injury or death" as:

> [A]n illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

42 U.S.C. § 300aa-33(5). As both Dr. Cloer and the government recognize, this definition does not provide definitive guidance for us on the specific argument put forward by Dr. Cloer. However, "[a]s a rule, a definition which declares what a term 'means' . . . excludes any meaning that is not stated." *Burgess v. United States*, 553 U.S. 124, 130 (2008) (quoting *Colautti v. Franklin*, 439 U.S. 379, 392-93 n.10 (1979)). Thus, we begin with a hesitation to read a causal link requirement into the term when no such link is included in the explicit statutory definition. Moreover, "[a] term appearing in several places in a statutory text is generally read the same way each time it appears." *Ratzlaf v. United States*, 510 U.S. 135, 143 (1994). As the term "vaccine-related injury" appears throughout the Vaccine Act, we must analyze the effects of adopting Dr. Cloer's contention that the term always requires recognition in the medical community of a causal link between the vaccine and the injury.

The Vaccine Act provides a Vaccine Injury Table of vaccines and the injuries commonly associated with the use of each vaccine. *See* 42 U.S.C. § 300aa-14; *see also* 42 C.F.R. § 100.3(a) (containing updated Table). For injuries listed in the Table, generally referred to as "Table injuries," a petitioner need only prove that the first symptom or manifestation of onset occurred within the time period after vaccine administration set forth in the

Vaccine Injury Table in order to receive compensation, *see* 42 U.S.C. § 300aa-11(c)(1)(C)(i), unless the government can prove that a factor unrelated to the vaccination actually caused the illness, disability, or condition. *See Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citing 42 U.S.C. § 300aa-13(a)(1)(A), (B)). For these injuries recognized by the medical community as linked to vaccine administration, Congress eliminated the petitioner's burdensome proof requirement. For "non-Table injuries," a petitioner must prove the injury was caused by the vaccine. *See* 42 U.S.C. § 300aa-11(c)(1)(C)(ii).

A "vaccine-related injury" is the subject of the petition for compensation in both Table and non-Table cases. For Table injury cases, the statute specifically defines for each vaccine the "vaccine-related" injuries for which compensation is assured. For example, a petitioner who suffers from a symptom of an anaphylactic shock injury within four hours of receiving a DTaP vaccine is presumed to have been injured by the vaccine. *See* 42 C.F.R. § 100.3(a). But for non-Table injuries, a petitioner must file an affidavit and supporting documentation demonstrating that the "vaccine-related injury" for which compensation is sought was caused by a vaccine.[3]

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[3] We note that a petitioner's pleading burden is, of course, lower than the preponderance burden that must be met in order to receive compensation. *See* 42 U.S.C. § 300aa-13(a)(1) ("Compensation shall be awarded to a petitioner if the special master or court finds . . . (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition."). To meet the preponderance standard, a petitioner must show that the vaccination brought about her injury by providing: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and

The statute of limitations for the Act uses the same "vaccine-related injury" terminology.

> In the case of . . . a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, *if a vaccine-related injury occurred* as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury . . . .

42 U.S.C. § 300aa-16(a)(2) (emphasis added).

Dr. Cloer would read "vaccine-related injury" throughout the Vaccine Act to require that the alleged injury must be objectively recognized by the medical community as related to the vaccine before it can be deemed a "vaccine-related injury." Accordingly, the statute of limitations would not begin to run on prospec-

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effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. A petitioner only needs to "provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case" and "the explanation need only be legally probable, not medically or scientifically certain." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quotation marks omitted).

Congress clearly contemplated that petitioners might not be able to meet the burden to demonstrate causation-in-fact by preponderance at the time the petition is filed. This is easily seen in the statute as a Vaccine Act petitioner, even if ultimately unsuccessful, can still receive compensation to cover reasonable attorneys' fees and other costs incurred in the proceeding "if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim." 42 U.S.C. § 300aa-15(e)(1).

tive petitioners until after this recognition is established. However, the statute is clear that only "*[a] person who has sustained a vaccine-related injury* . . . may, if the person meets the requirements of subsection (c)(1) of this section [listing the required elements of a petition], file a petition for compensation under the Program." 42 U.S.C. § 300aa-11(b)(1)(A) (emphasis added). Under Dr. Cloer's view that no vaccine-related injury exists until there is consensus in the medical community of a causal link between an injury and a vaccine, the key element of the petition for compensation—the vaccine injury—does not arise until the requisite medical consensus exists. For example, in this case, it is agreed that even now there is not medical consensus of a causal link between the Hep-B vaccine and MS. Thus, under Dr. Cloer's definition of vaccine-related injury, she, like the great majority of non-Table injury petitioners, would lack standing to file a petition until the requisite medical consensus arises. Any construction that would result in a party suffering from a non-Table injury to be unable to file a petition because the alleged injury is not recognized by the medical community at large cannot be what Congress intended.[4]

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[4] The first time an injury is causally linked with a vaccine often occurs as a result of a successful non-Table petition. Over time, as injuries occur throughout the population and are linked to a vaccine, the medical community begins to recognize a link between the vaccine and the injury. This can occur through studies published in medical journals or as a result of government research. Often, however, before the link is sufficiently established to become generally recognized by the medical community, petitioners are able to muster enough evidence to receive compensation from the Vaccine Program. *See, e.g., Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) ("[R]equiring 'objective confirmation' in the medical literature prevents 'the use of circumstantial evidence . . . and ne-

Further, settled law establishes a firm default rule that a cause of action arises at the same time the statute

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gates the system created by Congress' through the Vaccine Act.") (quoting *Althen, supra* note 4, 418 F.3d at 1279-80) (omission in original); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006) ("[R]equiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, *or general acceptance in the scientific or medical communities* to establish a logical sequence of cause and effect is contrary to [precedent].") (emphasis added). Finally, because a successful "causation in fact" petition can be the first established link between a vaccine and a non-Table injury, it must be allowed to be filed before an objective recognition is understood by the medical community at large.

As noted above, *Althen* sets forth the three pleading requirements for a non-Table injury petition. These requirements have not been insurmountable for petitioners seeking compensation for MS caused by the Hep-B vaccine. At least 35 petitions alleging MS caused by the Hep-B vaccine have resulted in public opinions to date, and at least 14 of those petitioners have been successful. Many of the successful petitioners filed their petitions in 1999. *See, e.g., Fisher v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-432V, 2009 WL 2365459 (Fed. Cl. Sp. Mstr. Jul. 13, 2009) (petition filed Jul. 2, 1999); *Adler v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-608V, 2008 WL 5068931 (Fed. Cl. Sp. Mstr. Nov. 18, 2008) (petition filed Aug. 4, 1999); *Doe/23 v. Sec'y of the Dep't of Health & Human Servs.*, 2008 WL 4865974 (Fed. Cl. Sp. Mstr. Oct. 16, 2008) (petition filed May 17, 1999); *Barillaro v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-408V, 2008 WL 2465794 (Fed. Cl. Sp. Mstr. May 28, 2008) (petition filed June 28, 1999); *Doe/13 v. Sec'y of the Dep't of Health & Human Servs.*, 2008 WL 926930 (Fed. Cl. Sp. Mstr. Mar. 31, 2008) (petition filed May 14, 1999); *Doe/07 v. Sec'y of the Dep't of Health & Human Servs.*, 2007 WL 3306493 (Fed. Cl. Sp. Mstr. Nov. 2, 2007) (petition filed Jul. 16, 1999); *Augustynski v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-611V, 2007 WL 3033614 (Fed. Cl. Sp. Mstr. Sep. 28, 2007) (petition filed Aug. 4, 1999); *Phippen v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-435V, 2006 WL 5631725 (Fed. Cl. Sp. Mstr. Dec. 5, 2006) (petition filed Jul. 2, 1999); *Werderitsh v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Sp. Mstr. May 26, 2006) (petition filed May 18, 1999).

of limitations begins to run on the cause. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 409, 418 (2005) ("Congress generally drafts statutes of limitations to begin when the cause of action accrues."). The Supreme Court has recognized that Congress is free to provide the "odd result" of a cause of action that arises at a time different from the beginning of a statute of limitations, *see Reiter v. Cooper*, 507 U.S. 258, 267 (1993), but only by explicitly rejecting the default rule. *See Dodd v. United States*, 545 U.S. 353, 359-60 (2005). Under Dr. Cloer's interpretation of a vaccine-related injury, her claim for compensation would accrue (thus letting her petition go forward) before medical consensus as to causation exists. To succeed, she must show that Congress meant to divorce the date of accrual of her cause of action from the date that the statute of limitations begins to run. She faces the heavy burden of proving that Congress intended the odd result of breaching the firm default rule. Nothing in the text of the Vaccine Act demonstrates that Congress made a deliberate choice to allow a cause of action for a vaccine-related injury to accrue before the Vaccine Act's statute of limitations begins to run.[5]

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[5] The foregoing discussion responds to arguments made by Dr. Cloer in her initial briefs and at oral argument before the panel concerning the meaning of "vaccine-related injury." In the en banc proceedings, she preserved the consensus argument from her initial briefs, but retreated somewhat from her initial stance, arguing that the statute of limitations runs and her cause of action arises instead upon "recognition" by the medical community of a causal link between an injury and a vaccine. Her "recognition" trigger requires less proof than consensus in the medical community. Her rephrasing thus keys accrual of her claim not to medical agreement as to cause, but to whether there is reason to know that a vaccine may have caused her injury. As rephrased, her argument depends upon a discovery rule being found in

In addition, we note an unintended result that would occur were we to accept Dr. Cloer's argument that the statute of limitations for a non-Table injury does not begin to run until the medical community at large recognizes a causal link between a vaccine and a claimed injury. Congress recognized that the Vaccine Injury Table could be revised such that a person not previously eligible for compensation might become eligible to seek compensation for the newly-recognized Table Injury. In such instances, Congress wrote a special statute of limitations that permits a claim for compensation under the revised Vaccine Injury Table if a vaccine-related death or injury occurred less than 8 years before the revision of the Vaccine Injury Table and the claim is filed within 2 years after the effective date of the revision. *See* 42 U.S.C. § 300aa-16(b). If Dr. Cloer's trigger for the statute of limitations for a non-Table injury were accepted, she and those similarly situated would enjoy a more generous statute of limitations than Congress provided for Table Injury petitioners, for whom causation is presumed. We do not think Congress would have intended such a result.

The correct interpretation of the term "vaccine-related injury" is plain from the language of the statutory provisions that set forth the statute of limitations and the requirements for a petition. For Table injury cases where causation is presumed, the vaccine-related injury is the injury specified in the Vaccine Injury Table for which a petitioner seeks compensation. For non-Table injury cases where the petitioner must establish causation, the vaccine-related injury is the injury which

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the Vaccine Act statute of limitations. We address that questions in part VI.A below.

the petitioner avers is caused by the vaccine. The statute of limitations on its face requires a petition for compensation to be filed within 36 months after the date of occurrence of the first symptom or manifestation of onset of vaccine related injury. The statutory language, however, begs the question of the test for recognition of the existence of a symptom or manifestation of onset of an injury. In short, who decides if a symptom or manifestation of an injury has occurred? We were faced with, and decided, that question in *Markovich*. 477 F.3d at 1360.

In that case, the parents of a child sought compensation for seizure disorders suffered by the child after administration of a vaccine. On the day of administration of the vaccine, July 10, 2000, the child began to rapidly blink her eyes. The eye-blinking episodes continued for more than a month and culminated in a grand mal seizure. *Id.* at 1354-55. Under recognized standards of the medical profession at large, the eye-blinking episodes were symptoms of the seizure activity for which compensation was sought. The government argued that the first of such symptoms, on July 10, 2000, triggered the statute of limitations and required dismissal of the petition, which had been filed more than three years from the July 10 date. The petitioners argued for a subjective test to determine when the first symptom occurs. Accordingly, they argued that the symptom of the injury had to be understood as such by the parents. Because they thought the first blinking episodes were simply everyday events meaning the child was tired, they argued that the statute of limitations did not begin to run until August 30, 2010, when they became aware that their child had an injury. Under their view of how a

symptom should be determined, their petition was timely. *Id.* at 1356-57.

Markovich thus resolved the dispute:

> A subjective standard that focuses on the parent's view would result in an uneven and perhaps overly broad application of the statute of limitations dependent entirely on the subjective perceptions of lay persons having widely varying degrees of medical awareness or training. On the other hand, an objective standard that focuses on the recognized standards of the medical profession at large treats petitioners equally, without regard to their individual medical awareness. An objective standard is consistent with the statutory requirement that the first symptom or manifestation of onset of the injury begins the running of the statute of limitations, as well as the cases . . . that have consistently construed the Vaccine Act to include subtle symptoms that would be recognizable to the medical profession at large but not necessarily to the parent.

477 F.3d. at 1360.

We thus held that the first symptom or manifestation of onset of a vaccine-related injury is "the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." *Id.* The analysis and conclusion in *Markovich* is correct. The statute of limitations in the Vaccine Act begins to run on the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury for which compensation is sought, and the symptom or manifestation of onset must be recognized as such by the medical profession at large.

B

In order to file a petition, a claimant must attest, *inter alia*, that she has "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." 42 U.S.C. § 300aa-11(c)(1)(D)(i). Dr. Cloer argues that because her symptoms were fleeting, she could never have met this requirement until late 2003 when her symptoms were continuous and related enough to be deemed "residual effects or complications" of her Hep-B vaccinations. The government responds that the petition requirements are wholly separate from the statute of limitations and should not be read to extend the filing date of the petition beyond 36 months.

We agree with the government that the 6 month requirement is a condition precedent to filing a petition for compensation, not a limitation on the 3 year statute of limitations. The 6 month provision is a petition content requirement to which no reference is made in the statute of limitations. Had Congress intended to adjust the statute of limitations in light of the petition content requirement, we think it would have done so in the statute of limitations. We thus agree with the Court of Federal Claims that there is no support for Dr. Cloer's argument in the text of the Act, nor any in the case law. Congress included the 6 month petition requirement "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." H.R. Rep. No. 100-391(I), at 699 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, -373. Thus, this provision, along with the other petition requirements, is intended to restrict eligibility to the compensation program, not

to act as a statutory tolling mechanism for the statute of limitations.

C

Finally, Dr. Cloer requested in her initial briefs that equitable tolling be made available and applied to the facts of her case, in spite of the binding precedent of *Brice*. Although the argument was rejected by the Chief Special Master and the Court of Federal Claims, and not addressed by the panel which initially heard the case, the en banc court decided to reconsider *Brice* through the lens of specific questions that were put to the parties. Equitable tolling is considered below, in parts VI.B and C.

VI

In an October 25, 2010 order, the court vacated its May 6, 2010 opinion and reinstated the appeal. We requested the parties to file new briefs addressing the following questions:

(a) Should the discovery rule, used for example in medical malpractice cases, *see United States v. Kubrick*, 444 U.S. 111, 120 (1979) and *TRW, Inc. v. Andrews*, 534 U.S. 19, 27-28 (2001), apply to 42 U.S.C. § 300aa-16(a)(2) so that the statute of limitations does not begin to run until the claimant has knowledge or reason to know of the cause of her injury?

(b) Should *Brice v. Secretary of Health & Human Services*, 240 F.3d 1367 (Fed. Cir. 2001) be overruled to permit equitable tolling of 42 U.S.C. § 300aa-16(a)(2)?

(c) If equitable tolling is permitted, do the circumstances of this case support equitable tolling?

Upon reviewing the briefs of the parties the court heard argument on May 10, 2011. We now address each question put to the parties.

A

Whether to incorporate a discovery rule in the Vaccine Act's statute of limitations requires us to decide when the statute of limitations is triggered. Absent a discovery rule, the plain words of the statute trigger the statute of limitations on the date of the first symptom or manifestation of onset of the injury claimed. If, instead, the statute of limitations does not begin to run until a petitioner knows or has reason to know a vaccine has caused her vaccine-related injury, the plain words of the statute must be adjusted. Whether or not to incorporate a discovery rule boils down to a matter of interpretation of the statute of limitations.[6]

As previously stated, the statute of limitations contained in the Vaccine Act reads:

> In the case of—
>
> . . .
>
> (2) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a

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[6] As a matter of caution, we must recognize and respect that a "statute of limitations is a condition on the waiver of sovereign immunity by the United States" and courts should be "careful not to interpret [a waiver] in a manner that would extend the waiver beyond what Congress intended." *Stone Container Corp. v. United States*, 229 F.3d 1345, 1352 (Fed. Cir. 2000) (quoting *Block v. North Dakota ex rel. Bd. of Univ. & Sch. Lands*, 461 U.S. 273, 287 (1983) (internal quotation omitted)). We have consistently followed this admonition when interpreting the Vaccine Act's statute of limitations. *See, e.g., Markovich*, 477 F.3d at 1360; *Brice*, 240 F.3d at 1370.

> vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury[.]

42 U.S.C. § 300aa-(16)(a). Dr. Cloer makes two arguments for why a discovery rule should be read into the Vaccine Act. First, she argues that the text of the statute of limitations amounts to a discovery accrual rule requiring a claimant to know both the fact and the cause of her injury. Second, she argues that the language of the Vaccine Act is compatible with an implied discovery accrual rule. *See TRW*, 534 U.S. at 27 ("[L]ower federal courts generally apply a discovery accrual rule when a statute is silent on the issue.") (quotation marks omitted); *see also Rotella v. Wood*, 528 U.S. 549, 555 (2000) ("Federal courts, to be sure, generally apply a discovery accrual rule when a statute is silent on the issue.").

For the reasons that follow, we conclude that the Vaccine Act does not itself contain a discovery rule, and, applying the relevant analytic tools provided by the Supreme Court, conclude also that a discovery rule cannot be read by implication into the Vaccine Act's statute of limitations. We first address Dr. Cloer's argument that the Act contains its own discovery rule.

Dr. Cloer specifically highlights the phrase "if a vaccine-related injury occurred as a result of the administration of [the] vaccine" in the statute of limitations. Dr. Cloer argues that the inclusion of this phrase in the statute means that a non-Table injury claim does not accrue until the claimant has knowledge that the injury

"occurred as a result of the administration of [the] vaccine." Otherwise, Dr. Cloer posits, the phrase would be superfluous. The government counters that the phrase is essential to breathe meaning into the term "vaccine-related injury" as used in the statute of limitations. The government reads the accrual of a non-Table injury (and thus the beginning of the statute of limitations) to arise on the "date of occurrence of the first symptom or manifestation of onset" of the injury the claimant alleges to be "vaccine-related" for having "occurred as a result of the administration of [the] vaccine."

As an initial matter, Dr. Cloer is correct that "we construe statutes, where possible, so as to avoid rendering superfluous any parts thereof." *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991). However, the clearly dominant language in the statute of limitations is "the date of occurrence of the first symptom or manifestation of onset." As the Supreme Court has noted, the date of the occurrence of the first symptom is forceful—"[t]here cannot be two first symptoms or onsets of the same injury"—and the first symptom "signal[s] the injury's onset." *Shalala v. Whitecotton*, 514 U.S. 268, 274 (1995). We do not think that dominant phrase can be overcome by inferring a discovery requirement from the phrase "occurred as a result of the administration of [the] vaccine." We therefore reject Dr. Cloer's argument that the statute of limitations already contains a discovery rule that would key the ac-

crual of a non-Table injury claim and the beginning of the statute of limitations to a claimant's discovery that the vaccine caused her injury.[7]

We now turn to whether the Vaccine Act statute of limitations is susceptible to an implied discovery rule. As a preliminary matter, we note that the Supreme Court has left open the question of whether a presumption exists that "all federal statutes of limitations, regardless of context, incorporate a general discovery rule unless Congress has expressly legislated otherwise." *TRW*, 534 U.S. at 27. Nonetheless, the Supreme Court noted in TRW, *id.*, that it had held in *Holmberg v. Armbrecht*, 327 U.S.392 (1946), that "where a plaintiff has been injured by fraud and remains in ignorance of it without any fault or want of diligence or care on his part, the bar of the statute of limitations does not begin to run until the fraud is discovered." 534 U.S. at 27 (quoting *Holmberg*, 327 U.S. at 397). The Supreme Court proceeded to note in *TRW* that "[t]he only other cases in which we have recognized a prevailing discovery rule, morever, were decided in two contexts, latent disease and medical malpractice, 'where the cry for [such a] rule is loudest.'" *Id.* (quoting *Rotella*, 528 U.S. at 555) (second alteration in original). As the guide for deciding

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[7] We note that Congress knows how to legislate an explicit discovery rule. For example, when providing a cause of action to quiet title of property in which the United States claims an interest, Congress mandated that "[a]ny civil action under this section . . . shall be barred unless it is commenced within twelve years of the date upon which it accrued. Such action shall be deemed to have accrued on the date the plaintiff or his predecessor in interest knew or should have known of the claim of the United States." 28 U.S.C. § 2409(g); *see also TRW*, 534 U.S. at 38 (Stevens, J., concurring) (discussing three additional examples of explicit discovery rules enacted by Congress).

whether to read a discovery rule into a federal statute of limitations, the Supreme Court held in *TRW* that Congress can "convey its refusal to adopt a discovery rule . . . by implication from the structure or text of the particular statute." *Id.* at 27-28.

The question we must decide is whether, in the context of a no-fault vaccine-injury remedy statute Congress, in the text of the Vaccine Act and considering its overall structure, conveyed its refusal to permit an implied discovery rule. We have already held that Congress did not write an explicit discovery rule into the statute.

Congress enacted the Vaccine Act statute of limitations against the backdrop of state law providing remedies for physical injuries. Indeed, Dr. Cloer points to that body of state law, noting that virtually all of the state laws on the subject incorporate discovery rules into their statutes of limitations. Those discovery rules look to the knowledge of a plaintiff to determine the date upon which the statute of limitations begins to run. From this body of state law, Dr. Cloer argues that Congress must have meant for the Vaccine Act statute of limitations to incorporate a discovery rule.

The contemporaneous existence of that body of state law, however, cuts against Dr. Cloer. First, that body of state law, dealing with fault liability, keys the accrual of the cause of action to the occurrence of the injury for which relief is sought. *See, e.g.*, Colo. Rev. Stat. §§ 13-80-106, 13-80-108 (enacting discovery rule for cause of action otherwise accruing at injury). As with the Federal Tort Claims Act, 28 U.S.C. § 2401(b), those state laws are understood to trigger their statutes of limitations upon the discovery of the existence and the

cause of the injury. *See United States v. Kubrick*, 444 U.S. 111, 120 (1979). We may presume that Congress is generally aware of the consequences of enacting a statute of limitations that runs from the date of occurrence of an injury. As noted above, Congress was presented the option of enacting a statute of limitations that would have run from the knowledge of the occurrence of a vaccine-related injury. *See* S. 827, 99th Congress § 2106(a) (1985). Had it done so, the parallel between state law and the Vaccine Act sought by Dr. Cloer would have been plausible. Instead, Congress made the deliberate choice to trigger the Vaccine Act statute of limitations from the date of occurrence of the first symptom or manifestation of the injury for which relief is sought, an event that does not depend on the knowledge of a petitioner as to the cause of an injury. This trigger confirms that a Vaccine Act cause of action accrues on that same date, not at a later date when a petitioner may have knowledge that the vaccine caused the injury. We need not decide whether the choice of Congress to bypass a statute of limitations comparable to the large body of state law shows a firm intent to bar, without more, a discovery rule in the Vaccine Act statute of limitations. But the choice made by Congress surely goes a long way to showing that Congress "conveyed its refusal to adopt a discovery rule."[8] *TRW*, 534 U.S. at 27.

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[8] The legislative history which we emphasize is not a matter of difference of opinion among legislators about what statutory language means, or individual statements by legislators. *See generally Garcia v. United States*, 469 U.S. 70, 75 (1984) (cautioning against reliance on legislators' "passing comments" and "casual statements" as indicating Congressional intent). Instead, it is a matter of pure fact that Congress had two clear and significantly differing concepts to choose from in writing the statute of limitations for the Vaccine Act. *Compare*

Examination of the overall structure of the Vaccine Act and its text buttresses our conclusion that a discovery rule cannot be read into the Vaccine Act statute of limitations. First and foremost, Congress selected a specific textual calendar date to trigger the statute of limitations. Nothing in that date, the first occasion of a symptom or manifestation of onset of the injury for which compensation is sought, asks for information about how much knowledge a petitioner had. It is a statutory date that does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition. We have recognized this in our previous cases. *See Markovich*, 477 F.3d at 1357 (rejecting the argument that eye blinking episodes were insufficient to start the statute of limitations because "the eye blinking symptom could not reasonably alert the Markoviches that anything was wrong."); *Wilkerson v. Sec'y of Dep't of Health & Human Servs.*, 593 F.3d 1343, 1345-46 (Fed. Cir. 2010) (rejecting a subjective standard for determining when the limitations period began to run based on the parent's perception and confirming an objective standard based on the medical profession's recognition of the existence of a symptom or manifestation of an injury).

H.R. 1780, 99th Congress § 2112 (1985) *with* S. 827, 99th Congress § 2106(a) (1985). Less significant but not unimportant is the additional fact that Congress was warned by Dissatisfied Parents Together, an interest group favoring the approach of S. 827, that the approach ultimately selected by Congress would trigger the statute of limitations regardless of when the claimant discovered the causal link between the injury and the vaccine. *See To amend the Public Health Service Act to provide for the compensation of children and others who have sustained vaccine-related injuries, and for other purposes: Hearing on S. 827 before the S. Comm. on Labor and Human Res.*, 99th Cong. 41 (1985) (statement of Jeffrey H. Schwartz, President of DPT).

The date of the first symptom or manifestation resonates throughout the Vaccine Act. For example, with regard to Table injury cases, the petitioner is supplied in the Vaccine Injury Table with a list of symptoms or manifestations and a list of dates associated with the time of occurrence of each of those symptoms or manifestations. The Table Injury petitioner uses the same single statute of limitations as a non-Table injury claimant, and has 36 months from the date of the first symptom or manifestation in which to file a petition for compensation.

As noted in Part I above, a significant motive for Congress in enacting the Vaccine Program was to provide an efficient, simple, and easy to administer system for processing vaccine injury claims. We think the triggering mechanism selected by Congress for the statute of limitations promotes those goals, whereas a discovery rule may not. Once it is understood that Congress intended a specific date, rather than a date that would vary depending on the knowledge of a petitioner, to trigger the statute of limitations, it is easily understood that time-consuming debates over when the statute of limitations started to run would not likely occur in processing a petition for compensation. When the date a symptom first occurred might sometimes be in issue, but the more complicated inquiry about whether petitioner knew or reasonably should have known of a causal connection only arises under Dr. Cloer's view of the statute. Further, "the date of occurrence of the first symptom or manifestation of onset" treats all petitioners equally, whereas under a discovery rule, the otherwise neutral 36 month time limit will vary from petitioner to petitioner.

A discovery rule necessarily adjusts the beginning of a statute of limitations to the circumstances of an individual case. The rule typically asks when a plaintiff knew or reasonably should have known of enough facts to proceed with her case. *Kubrick*, 444 U.S. at 120-22; *see also Kach v. Hose*, 589 F.3d 626, 634-35 (3d Cir. 2009); *Rakes v. United States*, 442 F.3d 7, 20 (1st Cir. 2006); *Fries v. Chicago & Nw. Transp. Co.*, 909 F.2d 1092, 1095 (7th Cir. 1990); 2 Calvin W. Corman, *Limitation of Actions* § 11.1.1 (1991). The discovery rule tethers accrual of the cause, and with it the start of the limitations period, to the knowledge of the plaintiff or of a reasonable actor in the plaintiff's position. The discovery rule is therefore an inherently personal, plaintiff-specific one. As a matter of both practice and design, a discovery rule treats different plaintiffs differently based on their personal circumstances. *Cascone v. United States*, 370 F.3d 95, 104 (1st Cir. 2004) ("The issue is whether a reasonable person *similarly situated* to the plaintiff would have known the necessary facts.").

In our view the personal, plaintiff-oriented approach of a discovery rule is antithetical to the simple, symptom-keyed test expressly required by the Vaccine Act's text. Such a conclusion is not surprising in light of the Vaccine Act's structure as a simplified no-fault administrative scheme. We note further that this conclusion is consistent with Congress's expressed desire that the Vaccine Act be "simple, and easy to administer" as well as "expeditious and fair." *See supra* part I (discussing legislative history). Under the Vaccine Act as written, two plaintiffs who receive the same vaccine on the same day, and who experience the same medically-recognized symptom of a vaccine-related injury shortly afterwards, also on the same day, begin their limitations

periods simultaneously. But under the more capacious analysis of the discovery rule, the start of the limitations period could vary widely based on each plaintiff's personal circumstances. We think these two results so different as to make implication of a discovery rule fundamentally incompatible with the text Congress enacted.

We therefore hold that Congress "conveyed its refusal to adopt a discovery rule . . . by implication from the text and structure" of the Vaccine Act. *TRW*, 534 U.S. at 27-28. The statute of limitations begins to run on a specific statutory date: the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury recognized as such by the medical profession at large.

B

In our second question for en banc briefing, we asked if *Brice* should be overruled to permit equitable tolling of 42 U.S.C. § 300aa-16(a)(2). We now answer that question in the affirmative. We therefore overrule *Brice* and hold that equitable tolling applies to the Vaccine Act. In Part C below, we reach and decide the ground on which Dr. Cloer seeks equitable tolling.

The Supreme Court observed in *John R. Sand & Gravel Co. v. United States*, 552 U.S. 130, 133 (2008), that "[m]ost statutes of limitations seek primarily to protect defendants against stale or unduly delayed claims." Limitations statutes of that nature do not implicate the jurisdiction of a court, and thus do not preclude relief from time filing limits by way of equitable tolling. The time limits in other statutes, the Supreme Court noted, have been read in the light of the statute's overall purpose as "more absolute, say as requiring a court to decide a timeliness question despite a waiver, or

as forbidding a court to consider whether certain equitable considerations warrant extending a limitations period." *Id.* at 133-34. As examples of such more absolute statutes, the Supreme Court mentioned statutes that "achieve a broader system-related goal, such as facilitating the administration of claims, *see, e.g., United States v. Brockamp*, 519 U.S. 347, 352-353 (1997), limiting the scope of a governmental waiver of sovereign immunity, *see, e.g., United States v. Dalm*, 494 U.S. 596, 609-10 (1990), or promoting judicial efficiency, *see, e.g., Bowles v. Russell*, 551 U.S. 205, 210-13 (2007)." *John R. Sand & Gravel*, 552 U.S. at 133. Whether a particular statute of limitations is treated as "jurisdictional" thus depends on the overall context of the statute. The term "jurisdictional" has no notable meaning in such contextual inquiries and is merely convenient shorthand for statutory limits that are absolute and require a court to consider timeliness questions without reference to equitable considerations. *Id.* at 133-34. The "jurisdictional" determination thus merges into the question of whether Congress intended to allow equitable tolling of the Vaccine Act's statute of limitations.[9]

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[9] In *Martin ex rel. Martin v. Secretary of Health & Human Services*, 62 F.3d 1403 (Fed. Cir. 1995), the parents of a child injured by polio vaccine sought attorneys' fees and costs under the Vaccine Act. 42 U.S.C. § 300aa-11(a)(6) bars a petition for compensation if the petitioner has previously filed a civil suit for damages for the same injury. Because the Martins had filed such a suit, their petition was dismissed for lack of subject matter jurisdiction. We thus viewed the barrier to suit in § 300aa-11(a)(6) as jurisdictional, and consequently held that the absence of jurisdiction over the Martins' petition for compensation removed jurisdiction over their application for attorneys' fees and costs. 62 F.3d at 1407. After we held in *Brice* that equitable tolling does not lie under the Vaccine Act, the Brices sought attorneys' fees and costs. The Court of Federal Claims, in the light of *Martin*,

Any analysis of whether equitable tolling lies against a federal statute of limitations begins with *Irwin v. Department of Veterans Affairs*, 498 U.S. 89 (1990). In that case, the Supreme Court established a presumption that all federal statutes of limitations are amenable to equitable tolling absent provision by Congress to the contrary. *Id.* at 95-96. *Irwin* left for decision in later cases whether when enacting specific statutes Congress rebutted the basic presumption in favor of equitable tolling. A leading case providing guidance on Congressional rebuttal is *United States v. Brockamp*, 519 U.S. 347 (1997). *Brockamp* framed the rebuttal question as "whether there is good reason to believe that Congress did not want equitable tolling to apply." 519 U.S. at 350. *Brockamp* detailed five factors for use in determining

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treated the Brices' failure to meet the statute of limitations as jurisdictional, and thus dismissed the Brices' attorneys' fee and costs request for lack of jurisdiction. On appeal, we too assumed, without analysis, that compliance with the Vaccine Act's statute of limitations is a jurisdictional requirement, and affirmed the Court of Federal Claims decision. *Brice v. Sec'y of Health & Human Servs.*, 358 F.3d 865, 869-70 (Fed. Cir. 2004) ("second *Brice*").

Dr. Cloer brought *Martin* and the second *Brice* decision to our attention, pointing out that the second *Brice* decision merely assumed that the statute of limitations is jurisdictional, and asking that we clarify the issue. Notably, the government does not rely on the second *Brice* decision; indeed, it does not assert that the statute is "jurisdictional" and thus inhospitable to equitable tolling.

The only purpose of the statute of limitations in the Vaccine Act is to protect the government from stale or unduly delayed claims. Whether viewed from the overall purpose perspective or, as demonstrated below, from the perspective of whether Congress barred equitable tolling by erecting a jurisdictional barrier, the answer is the same. There is no barrier to equitable tolling under 42 U.S.C. § 300aa-16(a)(2), and the statute of limitations is not jurisdictional. Previous law to the contrary is overruled.

whether Congress rebutted the basic *Irwin* presumption: the statute's detail, its technical language, its multiple iteration of the limitations period, its explicit inclusion of exceptions, and its underlying subject matter. *See Brockamp*, 519 U.S. 350-52. These same factors were considered by this court when it previously decided that equitable tolling is not available. Indeed, at that time and again in this case, the government agrees that only two of the factors cut against equitable tolling. First, the government argues that the Vaccine Act includes two specific exceptions to the basic 36 month statute of limitations. And second, the government argues that the Vaccine Act's detail as a whole reveals multiple strict deadlines.

The first exception to which the government refers provides for the situation when a petition for compensation is improperly filed as a tort claim in a state or federal court. Because a person seeking compensation for a vaccine-related injury must first file under the Vaccine Program, 42 U.S.C. § 300aa-11(a)(2), previous court filings elsewhere are improper and must be dismissed. The date such a dismissed action was filed "shall, for purposes of the limitations of actions prescribed by section 300aa-16 of this title [the 36 month period], be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action." 42 U.S.C. § 300aa-11(a)(2)(B).[10] This

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[10] The relief afforded to petitioners by 42 U.S.C. § 300aa-11(a)(2)(B) was not available to the petitioner in *Martin*. *See supra* n.9. That case dealt with 42 U.S.C. § 300aa-11(a)(6), which completely barred access to the Vaccine Program if a petition was filed after November 15, 1988, for a vaccine-related injury or death associated with administration of a vaccine before November 15,1988. In *Martin*, the vaccine was admin-

exception was relied on in *Brice* as a reason to deny equitable tolling.

The second exception to the basic limitations statute raised by the government concerns the provision in the Vaccine Act that deals with petitions for compensation filed after the Vaccine Injury Table is revised. For example, a person who was not eligible for compensation before the Vaccine Injury Table revision may file a petition for compensation under the revision, provided the petitioner's injury occurred no more than 8 years before the date of the revision and the petition is filed not later than 2 years after the effective date of the revision. 42 U.S.C. § 300aa-16(b). This exception was not discussed in *Brice*.

As for the overall structure of the Vaccine Act, the government points to the many strict time deadlines that regulate cases once they are started. In particular, the government points to the need for special masters to decide cases within 240 days after the filing of a petition, and the bar to suspension of proceedings for more than 150 days. *See* 42 U.S.C. § 300aa-12(d)(3)(A)(ii),(C).

The correct analysis of the government's "exceptions" points is informed by the Supreme Court's recent decision in *Holland v. Florida*, 130 S. Ct. 2549 (2010), of which the *Brice* court did not have the benefit. *Holland* answered in the affirmative whether the one-year statute of limitations on petitions for federal habeas corpus relief by state prisoners under the Antiterrorism and Effective Death Penalty Act of 1996 ("AEDPA") is subject to equitable tolling. The respondent in *Holland*

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istered in 1986 and the state court suit was brought on November 15, 1989. *Martin*, 62 F.3d at 1404.

argued that the AEDPA should be interpreted to foreclose equitable tolling because the statute has explicit exceptions to the basic statute of limitations. 130 S. Ct. at 2561. The Supreme Court "concede[d] that [the AEDPA] is silent as to equitable tolling while containing one provision that expressly refers to a different kind of tolling." *Id.* at 2561-62 (citing the "exception" as 28 U.S.C. § 2244(d)(2), which does not count against the one-year statute the time a petitioner has a pending request for post conviction relief, because the federal petition cannot be brought before exhaustion of state remedies). The Supreme Court held that Congress had to balance the interaction of state and federal participation in the underlying subject matter, and the "exception" thus is a special need, and as such negates the significance of the special exception for *Brockamp* factor analysis purposes. 130 S. Ct. at 2562.

Holland teaches that exceptions to statutes of limitations do not necessarily rebut the bedrock *Irwin* presumption in favor of equitable tolling. Exceptions, instead, must be understood in context, for, as in *Holland*, an exception may signal a beneficent Congressional act, not a rebuttal of the *Irwin* presumption. In the context of the Vaccine Act, the "exception" seen in 42 U.S.C. § 300aa-11(a)(2)(B) does not counsel against equitable tolling.

As noted above, before a tort suit can be brought for damages, a claimant must seek relief under the Vaccine Program. If a would-be petitioner mistakenly first files a traditional tort suit, the tort suit must be dismissed. 42 U.S.C. § 300aa-11(a)(2)(B). Recognizing that the result of a rule requiring dismissal of premature suits could leave a petitioner nonsuited due to different stat-

utes of limitations for state torts and the Vaccine Act, Congress included a special need provision that would allow the petitioner to benefit from the earlier state filing date when faced with the Vaccine Act's statute of limitations. Similarly, Congress included a provision that tolls state statutes of limitations during the pendency of Vaccine Program action. *See* 42 U.S.C. § 300aa-16(c). Thus, Congress created a system that provides for a petitioner to have equal access to the Vaccine Program and to state remedies once any filing occurs regardless of the forum.

We think it clear that Congress had a specific concern, unrelated to equitable tolling considerations, in enacting the "exception" in 42 U.S.C. § 300aa-11(a)(2)(B). This provision shows Congressional response to possible confusion regarding the new no-fault compensation system by minimizing the consequence of certain errors. This "exception" is driven by a special need, as was the case in *Holland*, and does not show a desire by Congress to bar equitable tolling.

We turn now to the statutory provision that permits a petition for compensation to be filed upon revisions to the Vaccine Injury Table. We reject the government's argument that this "exception" bars equitable tolling of the statute of limitations. This statutory provision is aimed at scientific advances in medicine that enable the establishment of new Table Injuries, for which causation will be presumed. Individual factual circumstances, the grist of equitable tolling claims, played no role in enactment of this provision. We think equitable tolling concepts lie in a different world from the opening to all vaccine recipients of a claim due to new medical knowledge. This "exception" too is easily understood as a special

need provision to address a Vaccine Program that moves forward in time with advances in medicine. Equitable tolling is not defeated by the wisdom of Congress to see into the future.

The remaining factor urged by the government to support its view that Congress rebutted the *Irwin* presumption concerns the detailed time limits governing processing of cases under the Vaccine Program. Those factors, identified above, relate to the speed with which the special master must move in processing cases. Such limits are tight, to be sure, and they serve to meet the Congressional goal of swift and efficient disposition of claims once a petition is filed. These time limits are designed to benefit the petitioner. If a petitioner were to cause some delay in processing of her petition because the government resists her request for equitable tolling, she could not be heard to complain if the time to decide her claim is greater than a petitioner who filed her petition within the 36 month limit. And any delay in getting the merits of a petition underway because of equitable tolling is no greater, if as great, as the delay that would be inherent in resolving disputes about whether a petitioner reasonably should have known of a causal link between her injury and a vaccination. Further, the 36 month period comports with traditional tort remedy statutes of limitations, and is not overly generous. *See United States v. Beggerly*, 524 U.S. 38, 48-49 (1998) (denying equitable tolling on an "unusually generous" 12-year statute of limitations.)

In sum, measuring the Vaccine Act by the standards in *Irwin*, *Brockamp*, and *Holland*, we see no reason to bar equitable tolling of the statute of limitations in the Vaccine Act, and therefore must conclude that there is

not "good reason to believe that Congress did not want the equitable tolling doctrine to apply." *Brockamp*, 519 U.S. at 350.

C

In the order setting this case for en banc decision, we asked the parties to address whether, if equitable tolling is permitted, the circumstances of this case support equitable tolling. Dr. Cloer took advantage of our invitation and argued, as she has throughout these proceedings, that equitable tolling is appropriate in this case on the ground that she first became aware of the causal link between her MS and the Hep-B vaccine in 2004 when she saw an article in a journal suggesting such a link. She asserts that it is inequitable and unfair to hold her to the 36 month filing period when she had no reason to know, before 2004, of the causal link between her injury and the Hep-B vaccine. She thus posits that equitable tolling in her case, and presumably in other future cases with similar facts, should be a substitute for the discovery rule.

In other words, Dr. Cloer individually asks for the same relief as a matter of equity that Congress has withheld from all petitioners as a matter of law. But we find no basis in equity for doing so. Dr. Cloer has put no argument before this court that, for example, she has been the victim of a fraud, or of duress. *See, e.g., Bailey v. Glover*, 88 U.S. 342, 349-50 (1874). Instead, we understand her to argue that the result reached in the analysis above is *ipso facto* unfair because it threatens to deprive her of her claim. That is not, in our view, the sort of circumstance that might merit equitable tolling. *See Pace v. DiGuglielmo*, 544 U.S. 408, 418 (2005) (noting that equitable tolling requires a litigant to have dili-

gently pursued his rights, but that "some extraordinary circumstance stood in his way"); *see also Irwin*, 498 U.S. at 96 (noting that equitable tolling is to be used "sparingly" in federal cases and has been limited to cases involving deception or the timely filing of a procedurally defective pleading).

While we recognize that our holding sharply limits Dr. Cloer's ability to be compensated under the Vaccine Act, this outcome is the result of a policy calculation made by Congress not to afford a discovery rule to all Vaccine Act petitioners and Dr. Cloer's failure to point to circumstances that could justify the application of equitable tolling to forgive her untimely claim. We thus hold that equitable tolling under the Vaccine Act due to unawareness of a causal link between an injury and administration of a vaccine is unavailable.[11]

Accordingly, the judgment below is

AFFIRMED.

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[11] In *Irwin*, the Supreme Court found for the first time that equitable tolling is presumptively available in all actions against the government, including the one asserted by Mr. Irwin. 498 U.S. at 95-96. Because the Court concluded that Mr. Irwin could not satisfy the stringent requirements of that doctrine, however, the Court affirmed the judgment the judgment against Mr. Irwin. *Id.* We follow a similar course here.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

Appeal from the United States Court of Federal Claims in 05-VV-1002, Judge Lawrence J. Block

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DYK, *Circuit Judge*, dissenting, with whom *Circuit Judges* NEWMAN, LINN, and REYNA join.

Contrary to the majority, I think it is quite clear that the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3743, 3755, Title III (1986) (codified at 42 U.S.C. § 300aa-1 to 34) [hereinafter the Vaccine Act], incorporates a discovery rule under which the limitations period does not begin to run until the claimant knew or should have known of a connection between the alleged injury and a vaccine.[1]

I

It is well established in both state and federal law that a discovery rule should be presumed for limitations

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[1] This does not mean, of course, that a definitive diagnosis of the alleged injury is required to trigger the statute of limitations, as this court made clear in *Marovich v. Sec'y of Health & Human Servs.*, 477 F.3d 1353, 1360 (Fed. Cir. 2007).

purposes for claims similar to those under the Vaccine Act. The Supreme Court has "recognized a prevailing discovery rule . . . in [the] two context[s] of latent disease and medical malpractice, 'where the cry for [such a] rule is loudest.'" *TRW Inc. v. Andrews*, 534 U.S. 19, 27 (2001) (quoting *Rotella v. Wood*, 528 U.S. 549, 555 (2000)). Application of a discovery rule is necessary in these circumstances because the very fact that the plaintiff "has been injured . . . may be unknown or unknowable until the injury manifests itself; and the facts about causation may be in the control of the putative defendant, unavailable to the plaintiff or at least very difficult to obtain." *United States v. Kubrick*, 444 U.S. 111, 122 (1979). Where the plaintiff has knowledge of both the injury and its cause, however, "[t]he prospect is not so bleak" because the plaintiff is no longer at the mercy of the defendant, who possesses specialized medical knowledge. *Id.* Six of our sister circuits have similarly held that, in the case of medical malpractice and similar actions, the limitations period generally does not begin to run until the plaintiff knew or should have known of both the injury and its cause.[2] *See also TRW*, 534 U.S. at 27

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[2] *See, e.g., Sell v. U.S. Dep't of Justice*, 585 F.3d 407, 409 (8th Cir. 2009) ("In medical malpractice cases . . . the cause of action accrues when the plaintiff discovers the nature and cause of his injury."); *Hensley v. United States*, 531 F.3d 1052, 1056 (9th Cir. 2008) (noting that, "[i]n certain circumstances, such as claims involving medical malpractice, accrual does not occur until a plaintiff knows of both the existence of an injury and its cause"); *Green v. United States*, 180 F. App'x 310, 313 (3d Cir. 2006) ("[W]hen the fact of injury alone is insufficient to put an injured party on notice of its cause, the Supreme Court has indicated that the accrual of the claim is delayed until the injured party discovers that cause."); *Waggoner v. United States*, 95 F. App'x. 69, 71 (5th Cir. 2004) ("[A] claim under the FTCA accrues when a plaintiff knows or reasonably should have known of 'the exis-

("[L]ower federal courts generally apply a discovery accrual rule when a statute is silent on the issue.") (internal quotation marks omitted); *Rotella*, 528 U.S. at 555 ("Federal courts, to be sure, generally apply a discovery accrual rule when a statute is silent on the issue . . . . ").

While the majority does not dispute that the Vaccine Act remedy is similar to, and replaces, a medical malpractice or similar remedy, it asserts that the application of a discovery rule to petitions under the Vaccine Act is inappropriate because such a rule would be inconsistent with the language and structure of the Act. Relying on the Supreme Court decision in *TRW*, the majority points out that "Congress can 'convey its refusal to adopt a discovery rule . . . by implication from the structure or text of the particular statute.'" Maj. Op. at 31 (quoting *TRW*, 534 U.S. at 27-28). The text and the structure of the Vaccine Act, however, do not suggest that Congress rejected a discovery rule. To the contrary, both the text and the structure of the Act confirm that Congress adopted the prevailing discovery rule approach.

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tence and the cause of his injury.'"); *Mix v. Delaware & Hudson Ry. Co.*, 345 F.3d 82, 86 (2d Cir. 2003) ("[A]n FELA action accrues when the plaintiff in the exercise of reasonable diligence knows both the existence and the cause of his injury.") (internal quotation marks omitted); *Price v. United States*, 775 F.2d 1491, 1493-94 (11th Cir. 1985) ("[A] medical malpractice claim under the FTCA accrues when the plaintiff is, or in the exercise of reasonable diligence should be, aware of both [his] injury and its connection with some act of the defendant."); *see also Kubrick*, 444 U.S. at 120-21 (noting government concession that in medical malpractice cases plaintiff must know of both injury and its cause).

A

Section 300aa-16(a)(2) of the Vaccine Act provides:

> [I]f a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.

42 U.S.C. § 300aa-16(a)(2). Notably, the statute does not provide that the limitations period commences on the date of the injury. Instead, the limitations period commences on the date of the "first *symptom or manifestation*" of a "*vaccine-related* injury," making clear that the statute of limitations is triggered only where the claimant knew or should have known of both the injury and its connection to the vaccine. 42 U.S.C. § 300aa-16(a)(2) (emphases added). As the majority recognizes, the terms "symptom" and "manifestation" suggest knowledge or reason to know on the part of the claimant.[3] Maj. Op. at 25. That knowledge requirement refers not merely to the existence of a vaccine-related injury, but to knowledge that the injury was related to the vaccine. In other words, the limitations period is not triggered by knowledge of the injury itself, but by the first event which would put the claimant on notice that a vaccine-related injury has occurred.

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[3] *See* Webster's Third New Int'l Dictionary 1375, 2318 (1986) (defining "manifestation" as "something that manifests or constitutes an expression of something else: a perceptible outward, or visible expression," and "symptom" as "something that indicates the existence of something else").

Indeed, the limitations provision makes clear that it is not triggered merely by the first symptom of an injury—the injury itself must be *related* to the vaccine (i.e., a "vaccine-related injury") and must occur "*as a result* of . . . a vaccine." 42 U.S.C. § 300aa-16(a)(2) (emphasis added). The statutory definition of "vaccine-related injury" confirms this point, defining "vaccine-related injury" as "an illness, injury, condition, or death *associated with* one or more of the vaccines set forth in the Vaccine Injury Table." *Id.* § 300aa-33(5) (emphasis added). At the time the Vaccine Act was passed, the word "associated" was defined as "closely connected, joined, or united." Webster's Third New Int'l Dictionary 132 (1986). Thus, in order for an injury to be "associated with" a vaccine, there must be some connection between the injury and the vaccine, and there must be a manifestation or symptom of such an injury, i.e., there must be knowledge or reason to know that the injury is vaccine-related.

The majority asserts that the text of the Vaccine Act is inconsistent with the application of a discovery rule because "the clearly dominant language in the statute of limitations is 'the date of occurrence of the first symptom or manifestation of onset.'" Maj. Op. at 30 (quoting 42 U.S.C. § 300aa-16(a)(2)). Because the majority finds this phrase to be "dominant," it fails to recognize that the phrase "first symptom or manifestation of onset" means nothing standing alone. It can be understood only by looking to the remainder of the language in the limitations provision, which links the "first symptom or manifestation" to "a vaccine-related injury" and requires that such injury occur "as a result" of a vaccine. *See* 42 U.S.C. § 300aa-16(a)(2).

The majority's novel "dominant language" approach to statutory interpretation is plucked out of thin air and is contrary to Supreme Court precedent, which makes clear that when interpreting a statute, the "[i]nterpretation of a word or phrase depends upon reading the whole statutory text." *Dolan v. United States Postal Serv.*, 546 U.S. 481, 486 (2006); *see also U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (explaining that "we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy"); *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991) ("[W]e construe statutes, where possible, so as to avoid rendering superfluous any parts thereof."); *Hornback v. United States*, 601 F.3d 1382, 1385 (Fed. Cir. 2010) (quoting *U.S. Nat'l Bank of Or.*, 508 U.S. at 455). The majority's rule that the limitations period begins to run on the "date of the occurrence of the first medically recognized symptom or manifestation of onset of the injury claimed by the petitioner," Maj. Op. at 4, simply rewrites the statutory language by leaving out the requirement that the injury be "vaccine-related" and occur "as a result" of a vaccine.

In an effort to support its decision to ignore the statutory text, the majority relies on legislative history supposedly demonstrating that Congress deliberately chose to trigger the limitations period from the date of the first symptom or manifestation of the alleged injury, regardless of whether there is an objective reason to suspect a causal connection between the alleged injury and the vaccine. Even under the questionable assumption that legislative history could support a reading contrary to the text of the statute, there is no such legislative history here. The majority cites two alternative

pieces of legislation considered by Congress—H.R. 1780 and S. 827. The House of Representatives version required, in language similar to that finally enacted, that claims under the Act be brought within "two years after the first manifestation of a vaccine-related injury," a formulation that also required the "first manifestation" be "vaccine-related." National Childhood Vaccine-Injury Compensation Act of 1985, H.R. 1780, 99th Cong. § 2112(a) (1985). The Senate version required that claims be brought "within 5 years after the occurrence of the compensable complication or residual effect of the illness, disability, injury, or condition listed in the Vaccine Injury Table." National Childhood Vaccine-Injury Compensation Act of 1985, S. 827, 99th Cong. § 2106(a) (1985). In the Senate bill, as in the final version of the Act, causation was presumed for injuries listed in the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-11(c)(1)(C)(i). The Senate version also permitted the filing of a petition after the time period specified if it was demonstrated that the claimant "did not know that such complication or effect was compensable under the program," or the claimant "was not provided the information required by section 2143." S. 827, § 2106(b). Section 2143(c)(9) required that persons receiving a vaccine listed in the Vaccine Injury Table be provided certain information, including "information on . . . the availability of the Program."

The majority urges that Congress' rejection of the limitations provision set forth in the Senate bill demonstrates that Congress intended the limitations period to be triggered by the first symptom or manifestation of the alleged injury, regardless of whether there is any reason to suspect a connection between the alleged injury and the vaccine. But Congress' rejection of the

exception contained in the Senate bill in no way demonstrates that Congress intended to reject the application of a discovery rule.

First, unlike the Vaccine Act, the Senate bill did not permit a claimant to recover for an injury unless the injury was listed in the Vaccine Injury Table.[4] The only role of causation was to permit claimants to recover for Table injuries even though the time requirements for onset of the injury were not met. *See* S. 827, § 2105(a)(2).[5] The Senate bill did not, however, in this or any other respect, provide an exception to the limitations period based on the claimant's lack of knowledge or reason to know that there was a causal connection between the alleged injury and the vaccine. Thus, the rejection of the Senate bill hardly suggests a rejection of a discovery rule requiring that the claimant know or have reason to know of a causal connection between the alleged injury and the vaccine.

Second, the exception to the limitations period in the Senate bill was not a discovery rule. It did not depend

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[4] Section 2103 permitted the award of compensation only where "there is an adequate demonstration that . . . the [claimant] sustained, or had significantly aggravated, any of the illnesses, disabilities, injuries, or conditions listed in the Vaccine Injury Table." S. 827, § 2103(a)(2)(A). Additionally, the bill defined the term "vaccine-related injury" only in terms of injuries appearing in the Vaccine Injury Table, stating specifically that "the term 'vaccine-related injury' means any injury . . . listed in the Vaccine Injury Table." *Id.* § 2164(20).

[5] The Senate bill set forth a Vaccine Injury Table containing specific vaccines, injuries, and time periods for the first symptom or manifestation of onset of a listed injury. *Id.* § 2105(a)(1). Where the claimant's first symptom did not occur within the specified time period, the claimant could nonetheless recover upon demonstrating that the injury was caused by the vaccine.

on what the claimant knew or should have known, but on what the claimant actually knew. The exception permitted the filing of a petition after the time period specified only if it was demonstrated that (1) at the time of the vaccine, the petitioner was not provided with, among other things, information about the Vaccine Injury Compensation Program; or (2) that the petitioner did not know that the complication or effect of the injury was compensable under the Program. *Id.* §§ 2106(b), 2143(c)(9). Neither of these exceptions was designed to address a situation in which the claimant had no reason to suspect a causal connection between the alleged injury and the vaccine. Instead, they were designed to deal with circumstances in which the claimant had no knowledge of the availability or scope of the Vaccine Injury Compensation Program. As a result, Congress' rejection of the Senate limitations provision, does not suggest that Congress rejected a discovery rule or intended the language in the limitations provision of the Vaccine Act to be read to mean something different than the plain language conveys.

B

The application of a discovery rule is compelled by both the structure and history of the Vaccine Act, as well as its language. If the limitations provision were interpreted not to incorporate a discovery rule, claimants like Dr. Cloer would be faced with the odd result that the limitations period would begin to run before a petition could be filed under the Act., i.e., before the cause of action accrued. The majority itself recognizes that "settled law establishes a firm default rule that a cause of action arises at the same time the statute of limitations begins to run on the cause." Maj. Op. at 21

(citing *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 409, 418 (2005)). Thus, absent an indication to the contrary, the limitations period begins when the cause of action accrues. *Graham Cnty.*, 545 U.S. at 418; *see also Reiter v. Cooper*, 507 U.S. 258, 267 (1993) (declining to permit the "odd result" that the accrual of a federal cause of action and the start of the limitations period arise at different times without "any such indication in the statute").

The Vaccine Act divides vaccine-related injuries into two types—those which appear in the Vaccine Injury Table ("Table injuries") and those that do not ("non-Table injuries"). *See* 42 U.S.C. § 300aa-11(c)(1)(C). The same limitations period applies to both Table and non-Table injuries. *See id.* § 300aa-16(a)(2). For Table injuries, there is no need for the petitioner to establish causation because causation is presumed for injuries listed in the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(i). But where, as here, a claimant seeks compensation for a "vaccine-related injury" not listed in the Table, the petition must contain, among other things, "an affidavit, and supporting documentation, demonstrating that the person who suffered such injury . . . sustained, or had significantly aggravated, any illness, disability, injury, or condition . . . which was *caused by* a vaccine." *Id.* § 300aa-11(c)(1)(C)(ii) (emphasis added). A claimant's cause of action does not accrue until the time at which the claim becomes enforceable.[6] Claims under the Vaccine Act become enforceable, or accrue, only when a claimant can file a petition demonstrating that

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[6] To "accrue" in the sense of a cause of action means "[t]o come into existence as an enforceable claim or right." *Black's Law Dictionary* 23 (9th ed. 2009).

the alleged injury was "caused by a vaccine." *Id.* §§ 300aa-11(a), (c). The legislative history makes clear that this requirement is not satisfied by a mere allegation that the injury was caused by the vaccine, i.e., the usual pleading standard. Instead, "evidence in the form of scientific studies or expert medical testimony is necessary." H.R. Rep. No. 99-908, at 15 (1986). Thus, in order for the limitations period to commence, the claimant must be able to file a petition. And in order to file a petition, the claimant must demonstrate a causal connection between the vaccine and the injury using "scientific studies or expert medical testimony." *See id.* As a result, the limitations period cannot begin to run until "scientific studies or expert medical testimony" demonstrating a possible connection between the vaccine and the injury are known or should be known to the claimant.

The majority urges that a discovery rule would make "the otherwise neutral 36 month time limit . . . vary from petitioner to petitioner," Maj. Op. at 35, and thus undermine this court's decision in *Markovich* that the statute of limitations begins to run at "the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large," 477 F.3d at 1360. Under a discovery rule, however, the statute of limitations is triggered when the claimant knew or should have known that an injury was vaccine related. Though a claimant's subjective knowledge is certainly sufficient to trigger the statute of limitations, *Markovich* makes clear that subjective knowledge is not required.

The remedial nature of the Vaccine Act also supports a discovery rule. The Supreme Court has long recognized the canon of construction that remedial legislation

should be construed liberally. *See, e.g., Atchison, Topeka & Santa Fe Ry. Co. v. Buell*, 480 U.S. 557, 561-62 (1987); *Peyton v. Rowe*, 391 U.S. 54, 65 (1968); *Cosmopolitan Shipping Co. v. McAllister*, 337 U.S. 783, 790 (1949); *Stewart v. Kahn*, 78 U.S. 493, 504 (1870). The Vaccine Act, which created "a new system for compensating individuals who have been injured by vaccines," H.R. Rep. No. 99-908, at 3, clearly falls into the category of remedial legislation. The Vaccine Act's compensation program was intended to be a "program under which awards [could] be made to vaccine-injured persons quickly, easily, and with *certainty and generosity*." *Id.* (emphasis added). It was "designed to work faster and with greater ease than the civil tort system." *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995) (citing H.R. Rep. No. 99-908, at 3-7). Thus, it is clear from the legislative history that Congress intended the Vaccine Act's compensation program to be *more generous* than the civil tort system.[7]

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[7] Developments in the past few years have demonstrated the importance of the right to sue for non-Table injuries. The Secretary has revised the Vaccine Injury Table to add only four vaccine-related injuries since the Vaccine Act was enacted in 1986. *See* National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7694 (Feb. 8, 1995) (adding "Chronic arthritis" as an injury associated with the MMR vaccine); National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II, 62 Fed. Reg. 7685, 7688 (Feb. 20, 1997) (adding "Brachial neuritis" as an injury associated with the DTP vaccine, "Thrombocytopenic purpura" and "vaccine-strain measles virus infection" as injuries associated with the MMR vaccine, and "vaccine-strain poliovirus infection" as an injury associated with the live poliovirus vaccine); National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table, 67 Fed. Reg. 48558, 48559-60 (Jul. 25, 2002) (adding "intussusception" as an injury associated with the live, oral, rhesus-based rotavirus vaccine). In each case, the Secretary noted that

At the time the Vaccine Act was enacted, a large number of states recognized a discovery rule under which the limitations period did not begin to run until the plaintiff knew or should have known of both the injury and its cause.[8] Thus, in these states, the statute of

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the addition of a particular injury is appropriate only where it "can reasonably be determined . . . to be caused . . . by certain vaccines." 62 Fed. Reg. at 7685; *see also* 67 Fed. Reg. at 48558 (stating that the proposed revisions were "based upon the Secretary's determination that the [injury] can reasonably be determined in some circumstances to be caused by [a specific vaccine]"); 60 Fed. Reg. at 7681 (declining to add certain injuries allegedly related to the DTP vaccine because the Secretary "could not 'reasonably determine' that a causal connection exists"). Additionally, the Secretary has stated that the addition of an injury to the Vaccine Injury Table is inappropriate "[w]here [the] scientific research concerning the relationship between a disorder and a vaccine is incomplete or nonexistent." 62 Fed. Reg. at 7686.

[8] *See, e.g., Anson v. Am. Motors Corp.*, 747 P.2d 581, 584 (Ariz. Ct. App. 1987) (holding that "a cause of action does not 'accrue' until a plaintiff discovers or by the exercise of reasonable diligence should have discovered that he or she has been injured by the defendant's negligent conduct"); *Yamaguchi v. Queen's Med. Ctr.*, 648 P.2d 689, 693 (Haw. 1982) (same); *Barnes v. A.H. Robins Co.*, 476 N.E.2d 84, 87-88 (Ind. 1985) (same); *Louisville Trust Co. v. Johns-Manville Prods. Corp.*, 580 S.W.2d 497, 501 (Ky. 1979) (same); *Penn v. Inferno Mfg. Corp.*, 199 So. 2d 210, 219 (La. Ct. App. 1967) (same); *Baysinger v. Schmid Prods. Co.*, 514 A.2d 1, 3-4 (Md. 1986) (same); *Olsen v. Bell Tel. Labs., Inc.*, 445 N.E.2d 609, 611-12 (Mass. 1983) (same); *Cullender v. BASF Wyandotte Corp.*, 381 N.W.2d 737, 739 (Mich. Ct. App. 1985) (same); *Ahearn v. Lafayette Pharmacal, Inc.*, 729 S.W.2d 501, 503-504 (Mo. Ct. App. 1987) (same); *Thompson v. Neb. Mobile Homes Corp.*, 647 P.2d 334, 338 (Mont. 1982) (noting that statute of limitations begins to run on products liability claims when the plaintiff knew or should have known of both the injury and the defect); *Vispisiano v. Ashland Chem. Co.*, 527 A.2d 66, 71-72 (N.J. 1987) (holding that the statute of limitations begins to run when the plaintiff knew or should have known of both the injury and its cause); *O'Stricker v. Jim Walter Corp.*, 447 N.E.2d 727, 732 (Ohio 1983) (same); *Daugherty v. Farmers Coop. Ass'n*,

limitations on a vaccine-injury claim would not run until the claimant knew or should have known that there was a causal connection between the alleged injury and the vaccine. Under the majority's reading of the limitations provision, however, the Vaccine Act may be far less generous than the remedy afforded by the civil tort system, which generally applies a discovery rule to injuries like the ones at issue here. A claimant who is legitimately injured by a vaccine will nonetheless be barred from filing a petition simply because science has not advanced enough prior to the end of the three-year period following his or her first symptom to furnish a reason to suspect a connection between the injury and the vaccine. This simply cannot be the result intended by Congress when it set out to establish a "program under which awards [could] be made to vaccine-injured persons . . . with certainty and generosity." H.R. Rep. No. 99-908, at 3.

In any event, it seems quite unlikely that Congress intended the Vaccine Act's statute of limitations to effectively bar more generous state remedies that utilize a discovery rule, but that is also the effect of the majority's decision. The Vaccine Act was not intended to bar state remedies, but to provide an *additional* system for vaccine injury compensation which would "lessen the number of lawsuits against manufacturers." H.R. Rep. No. 99-908, at 12 (1986). This was accomplished by "requir[ing] that a person with an injury resulting from a vaccine . . . file a compensation petition and go

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689 P.2d 947, 950-51 (Okla. 1984) (same); *Burnside v. Abbott Labs.*, 505 A.2d 973, 987-88 (Pa. Super. Ct. 1985) (same); *Woods v. Sherwin-Williams Co.*, 666 S.W.2d 77, 78-79 (Tenn. Ct. App. 1983) (same); *Olson v. A.H. Robins Co.*, 696 P.2d 1294, 1298-99 (Wyo. 1985) (same).

through the compensation program before proceeding with any litigation against the manufacturer." *Id.* Congress' intent to preserve state law remedies is clearly expressed in § 300aa-16(c) of the Vaccine Act, which provides for a stay of state limitations periods when a petition for compensation is filed under the Vaccine Injury Compensation Program. *See* 42 U.S.C. § 300aa-16(c). But in states that recognize a discovery rule, that remedy is likely unavailable under the majority's view.

The Vaccine Act plainly requires that a claimant seek a remedy from the Vaccine Injury Compensation Program before attempting to pursue state law claims. *See* 42 U.S.C. § 300aa-11(a)(2); H.R. Rep. No. 99-908, at 14 (stating that claimants "must complete the compensation proceeding . . . *before* pursuing a civil action"); *see also Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1075 (2011). Where the claimant does not do so, the Act requires that the suit be dismissed by the state court. 42 U.S.C. § 300aa-11(a)(2)(B); *see also* H.R. Rep. No. 99-908, at 14. But the remedies available under the Vaccine Act are barred by the majority's view if more than thirty-six months have passed since the claimant's first symptom or manifestation of the injury. Thus, without the benefit of a discovery rule under the Vaccine Act, the claimant will be barred from filing a federal petition even though the state statute of limitations incorporating a discovery rule will not have run. The apparent result is that the state remedy will be barred for failure to file a petition under the Vaccine Act. It is incredible to think that the Vaccine Act was intended to

foreclose the very state law remedies that it was designed to preserve and augment.[9]

In the end, there is nothing in the structure or history of the Vaccine Act that renders a discovery rule inappropriate. In fact, the structure and history of the Act not only confirm, but compel the conclusion that a discovery rule is appropriate.[10] Failure to adopt a discovery rule will create a situation in which a claimant will be unfairly barred from filing a petition even if he or she never knows or has reason to know that a claim ex-

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[9] The majority makes the strange argument that the failure of the Vaccine Act to tie the limitations period to "occurrence of the injury," as do state discovery statutes, somehow manifests a rejection of the discovery rule. Maj. Op. at 32. The fact that Congress chose to be more explicit about the discovery rule than state statutes hardly reflects a different policy choice.

[10] The majority's sole structural argument is based on the fact that a discovery rule would provide claimants like Dr. Cloer with a more generous limitations period than that provided for claimants seeking compensation when a new injury is added to the Vaccine Injury Table. The majority asserts that it would be incongruous for claimants asserting non-Table injuries to "enjoy a more generous statute of limitations than . . . Table Injury petitioners, for whom causation is presumed." Maj. Op. at 23. But the different treatment of the statute of limitations for Table and non-Table injuries makes eminent sense. Claimants asserting Table injuries have constructive notice of the vaccine-related nature of their injuries. Claimants asserting non-Table injuries, however, have no such notice. Based on the standards espoused by the Secretary, an injury may be added to the Vaccine Injury Table only where there is sufficient evidence to support a determination that the injury is caused by a certain vaccine. *See supra* note 7. If evidence of a causal connection has not advanced to that point, claimants will not have the benefit of constructive notice or any presumption of causation. In those circumstances, it is not at all incongruous that the statute of limitations should not begin to run until the claimant knew or should have known that the injury is vaccine-related.

ists. Contrary to the majority's assertion, a discovery rule does not result in disparate treatment of similarly situated claimants, but ensures equitable treatment of all claimants.

II

The injustice of the majority's approach is amply demonstrated by the circumstances in this case. In Dr. Cloer's case, there is no dispute that the first symptom or manifestation of injury occurred in May 1997 when she experienced a Lhermitte sign, which is recognized by the medical profession as a common symptom of MS. The government has submitted no evidence, however, that Dr. Cloer had reason to suspect a connection between multiple sclerosis ("MS") and the Hepatitis B vaccine before 2004. Under the majority's reading of the Act, the limitations period on Dr. Cloer's claim began running on the date of her first symptom of MS, which occurred more than four years before her cause of action accrued. There is simply no indication that Congress intended that the limitations period begin before she had the information necessary to file a petition.

APPENDIX C

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT-APPELLEE

Oct. 25, 2010

ORDER

Appeal from the United States Court of Federal Claims in 05-VV-1002, Judge Lawrence J. Block

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Before: RADER, *Chief Judge*, NEWMAN, LOURIE, CLEVENGER*, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, *Circuit Judges*.

PER CURIAM.

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* Judge Clevenger participated only in the decision on panel rehearing.

Respondent-Appellee filed a combined petition for panel rehearing and rehearing en banc. The panel requested a response from Petitioner-Appellant.

The petition for rehearing was considered by the panel that heard the appeal,** and thereafter the petition for rehearing en banc and the response were referred to the circuit judges who are authorized to request a poll on whether to rehear the appeal en banc. A poll was requested, taken, and the court has decided that the appeal warrants en banc consideration.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition of Respondent-Appellee for panel rehearing is denied.

(2) The petition of Respondent-Appellee for rehearing en banc is granted.

(3) The court's May 6, 2010 opinion is vacated, and the appeal is reinstated.

(4) The parties are requested to file new briefs addressing the following three questions:

(a) Should the discovery rule, used for example in medical malpractice cases, *see United States v. Kubrick*, 444 U.S. 111, 120 (1979) and *TRW, Inc. v. Andrews*, 534 U.S. 19, 27-28 (2001), apply to 42 U.S.C. § 300aa-16(a)(2) so that the statute of limitations does not begin to run until the claimant has knowledge or reason to know of the cause of her injury?

** Chief Judge Michel, who was on the original merits panel, retired on May 31, 2010 and did not participate in the decision on rehearing.

(b) Should *Brice v. Secretary of Health and Human Services*, 240 F.3d 1367 (Fed. Cir. 2001) be overruled to permit equitable tolling of 42 U.S.C. §300aa-16(a)(2)?

(c) If equitable tolling is permitted, do the circumstances of this case support equitable tolling?

(5) This appeal will be heard en banc on the basis of the originally filed briefs and additional briefing ordered herein. The court will determine whether oral argument is appropriate after reviewing the briefs. An original and thirty copies of all originally filed briefs shall be filed within 20 days from the date of filing of this order. An original and thirty copies of new en banc briefs shall be filed, and two copies of each en banc brief shall be served on opposing counsel. Respondent-Appellee's en banc brief is due within 45 days from the date of this order. Petitioner-Appellant's en banc response brief is due within 40 days of service of Respondent-Appellee's new en banc brief, and Respondent-Appellee's reply brief, if any, is due within 15 days of service of Petitioner-Appellant's response brief. Briefs shall adhere to the type-volume limitations set forth in Federal Rule of Appellate Procedure 32 and Federal Circuit Rule 32.

(6) Briefs of amici curiae will be entertained, and any such briefs may be filed without leave of court or the parties' consent but otherwise must comply with Federal Rule of Appellate Procedure 29 and Federal Circuit Rule 29.

(7) If needed, oral argument will be held at a time and date to be announced later.

FOR THE COURT

Oct. 25, 2010
Date

/s/ JAN HORBALY
JAN HORBALY
Clerk

cc: Mari C. Bush, Esq.
Anisha S. Dasgupta, Esq.

APPENDIX D

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT-APPELLEE

Decided: May 6, 2010

OPINION

Appeal from the United States Court of Federal Claims in Case No. 05-VV-1002, Judge Lawrence J. Block

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Before: MICHEL, *Chief Judge*, CLEVENGER and DYK, *Circuit Judges*.

Opinion for the court filed by *Chief Judge* MICHEL. Dissenting opinion filed by *Circuit Judge* CLEVENGER.

MICHEL, *Chief Judge*.

Petitioner-appellant Melissa Cloer, M.D., appeals the decision of the United States Court of Federal Claims.

Cloer v. Sec'y of Health & Human Servs., 85 Fed. Cl. 141 (Fed. Cl. 2008). The decision affirmed the Chief Special Master's report, which denied Dr. Cloer's petition for compensation under the Vaccine Injury Compensation Program ("Vaccine Program") established by the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act"), because it was time-barred. *See Cloer v. Sec'y of Dep't of Health & Human Servs.*, No. 05-1002V (Fed. Cl. May 15, 2008).

This case presents the question of whether the Vaccine Act's statute of limitations, 42 U.S.C. § 300aa-16(a)(2), begins running where a claimant experiences a symptom of injury, but where the medical community at large does not recognize that the symptom is related to a vaccine and the claimant has not received medical information suggesting a connection. We hold that the statute of limitations does not begin running in such cases. Thus, we reverse and remand.

I. BACKGROUND

Plaintiff-appellant Melissa Cloer is a physician who is disabled due to multiple sclerosis ("MS"). She had no significant medical issues prior to exhibiting symptoms of demyelinating disease. Dr. Cloer received three Hepatitis B ("Hep-B") immunizations at the University of Missouri Student Health Center. After her first two vaccinations on September 3, 1996 and November 11, 1996, Dr. Cloer experienced some numbness and tingling. Dr. Cloer received her third Hep-B vaccination on April 3, 1997.

About a month after her final vaccination, Dr. Cloer began to experience an electric-like shock sensation in her spine. Medical professionals call this sensation a

Lhermitte sign, a common symptom of MS. In September and October 1997, petitioner also lost sensation in her left arm and left hand. Dr. Cloer consulted with her primary care physician, Dr. Pereira, who prescribed Motrin. The symptoms resolved over a short period of time.

When Dr. Cloer experienced additional problems in 1998, she returned to Dr. Pereira. Dr. Cloer underwent further testing, including a magnetic resonance imaging (MRI) scan on May 12, 1998. The MRI scan indicated that possible diagnoses for Dr. Cloer included MS, lyme disease, acute disseminating encephalomyelitis, or other demyelinating processes. A May 15, 1998 medical record specifically noted, "Probable early inactive non-progressive CNS [central nervous system] demylination/MS. . . ."

In 1998, Dr. Cloer was referred to a neurologist, Dr. Meyer, with a specialty in the diagnosis and treatment of MS. Dr. Meyer treated appellant in 1998 for "singular sclerosis" or "early inactive non-progressive CNS demyelinating disease." Dr. Cloer was given a "provisional" diagnosis of MS on November 26, 2003 by her treating neurologist Dr. Wood subsequent to his obtaining Dr. Cloer's medical history and the results of an MRI examination.

In May 2004, Dr. Cloer applied for and was awarded monthly Social Security disability benefits due to her medical condition. As part of her eligibility for benefits, James P. Metcalf, M.D., conducted a comprehensive medical examination and noted that appellant "first beg[a]n to have some symptoms consistent with MS in 1997," although her "symptoms waxed and waned until

the fall of 2003 when she beg[a]n to have manifestations of the full blown disease."

Dr. Cloer first became aware of an association between MS and the Hep-B vaccine when she read an editorial and prospective French study in the September 2004 issue of *Neurology*. Dr. Cloer reported to the Vaccine Adverse Event Reporting System (VAERS) on October 11, 2004 that she experienced numbness and tingling after her first two Hep-B vaccinations.

On September 16, 2005, Dr. Cloer filed a claim for compensation under the Vaccine Act, alleging that her Hep-B vaccinations caused or significantly aggravated her latent MS condition. On December 1, 2005, respondent-appellee Health and Human Services ("HHS") moved to dismiss the petition because it was filed after the expiration of the statutorily prescribed limitations period.

Dr. Cloer relied upon affidavits and testimony from Dr. Meyer, a recognized expert in MS. Dr. Meyer explained that when he evaluated Dr. Cloer in 1998 her symptoms were consistent with but not independently diagnostic for clinically definite MS. He noted that symptoms of MS could occur well before a diagnosis of MS is made. Dr. Meyer testified that, in retrospect, the first sign of MS was the Lhermitte sign that the appellant experienced in 1997.

Dr. Meyer did not believe, or even consider, that Dr. Cloer had suffered a vaccine injury when he evaluated her in 1998. Dr. Meyer did not become aware of the association between MS and Hep-B immunization until he was contacted by Dr. Cloer's counsel in late 2005. Dr. Meyer testified that a member of the medical community at large would not have recognized or believed Dr.

Cloer had a vaccine injury as of 1999. Having reviewed Dr. Cloer's prior medical records, Dr. Meyer found no indication of a link between her MS and the Hep-B immunizations before 2004. Dr. Meyer's testimony was not rebutted by any expert.

In 2007, the Chief Special Master conducted a telephonic hearing to take Dr. Meyer's testimony. The Chief Special Master issued his decision on May 15, 2008, determining that the first symptom, manifestation of onset, or significant aggravation of Dr. Cloer's MS was the Lhermitte's sign she experienced in 1997. Because Dr. Cloer filed her Vaccine Act petition on September 16, 2005, more than 36 months later, the Chief Special Master dismissed the petition as untimely. The Court of Federal Claims affirmed the Chief Special Master's decision.

Dr. Cloer timely appealed to the Federal Circuit. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(3).

II. DISCUSSION

A.

Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 42 U.S.C. § 300aa-12(e)(2)(B); *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1277 (Fed. Cir. 2005). We review legal determinations of the Court of Federal Claims *de novo*. *Althen*, 418 F.3d at 1278. To the extent that the Court of Federal Claims adopts factual findings made by the special master, we accord them the same deference as the Court of Federal Claims and review them under the arbitrary and capricious standard as provided in the

statute. *Munn v. Sec'y of the Dep't of Health & Human Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992). While we owe no deference to either the special master or the trial court on questions of law, *Whitecotton v. Sec'y of Health & Human Servs.*, 81 F.3d 1099, 1106 (Fed. Cir. 1996), we review factual findings for clear error, *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1523 (Fed. Cir. 1991).

B.

Congress established the Vaccine Act to increase the safety and availability of vaccines. *See* 42 U.S.C. § 300aa-1. As part of the Vaccine Act, the Vaccine Program permits claimants to petition to receive compensation for vaccine-related injuries. *See* § 300aa-100(a). The Vaccine Injury Table lists vaccines that are covered under the Vaccine Act. *See* §§ 300aa-11(c)(1)(C)(ii), 300aa-14. The Vaccine Injury Table also lists injuries that may arise from these vaccines, which are referred to as Table injuries. § 300aa-14. Other injuries, including MS, are not listed in the Vaccine Injury Table and referred to as non-Table injuries. § 300aa-11(c)(1)(C)(ii).

The Vaccine Act sets forth a statute of limitations:

> In the case of . . . a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.

§ 300aa-16(a)(2). The question in this case is whether the 36 month period commences where a petitioner experiences the first symptom of an injury, but where the medical community at large does not recognize that the symptom is related to a vaccine and the claimant has not received medical information suggesting such a connection. If so, Dr. Cloer's appeal is time-barred because she experienced the first symptom of MS in 1997 but did not file her claim until 2005.

Dr. Cloer argues that her appeal cannot be time barred because the "first symptom or manifestation of onset," for the purposes of § 300aa-16(a)(2), is "the first event objectively recognizable as a sign of vaccine injury by the medical profession at large." *See Markovich v. Sec'y of Heath and Human Servs.*, 477 F.3d 1353 (Fed. Cir. 2007). Dr. Cloer interprets *Markovich* to mean that the medical community at large needs to recognize a link between the injury and the vaccine for the statute of limitations to begin running. We generally agree.

We begin with an analysis of *Markovich*, where this court considered the standard that should be applied in determining the date of "the occurrence of the first symptom or manifestation of onset. . . ." *Id.* at 1356. The Markoviches' daughter, Ashlyn, received a series of vaccinations on June 10, 2000, when she was approximately two months old. *Id.* at 1354. That same day, the Markoviches observed that Ashlyn began to rapidly blink her eyes, but they did not recognize that it was a first symptom of vaccine-related seizures. *See id.* On August 30, 2000, Ashlyn became unresponsive for about twenty minutes, during which time all of Ashlyn's extremities jerked aggressively. *Id.* at 1354-35. Ashlyn was treated at the Fairview Ridge Emergency Room,

where she was diagnosed with having a grandmal seizure. *Id.* at 1355.

The Markoviches argued that the standard for the statute of limitations should be subjective and begin running on August 30, 2000, the date they became aware of an injury. *Id.* at 1356. This court disagreed, holding that an objective standard was consistent with the Vaccine Act language that the statute is triggered by the "*first* symptom *or* manifestation of onset." *Id.* at 1358, 1360. The use of the words "first" and "or" require that the statute of limitations commence with whichever event (i.e., symptom or manifestation of onset) occurs first. *Id.* at 1358. Thus, this court held that the "'first symptom or manifestation of onset,' for the purposes of § 300aa-16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." *Id.* at 1360. Because Ashlyn's eye blinking episode was objectively recognizable by the medical profession at large as constituting the first evidence of vaccine injury onset, the statute of limitations began on that date. *Id.*

Markovich confirms that, under § 300aa-16(a)(2), in general, a symptom must be recognizable by the *medical community at large* as constituting a *vaccine-related injury*. As this court expressly held, the limitations period begins at the "first event objectively recognizable as a sign of a *vaccine injury* by the *medical profession at large*." *See id.* (emphasis added). This holding also is consistent with the plain language of the statue of limitations, which specifically applies to injuries that are vaccine-related:

> In the case of . . . a vaccine set forth in the Vaccine Injury Table which is administered after October 1,

> 1988, if a *vaccine-related injury* occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of *such injury*.

§ 300aa-16(a)(2) (emphasis added). Thus, we hold that, in general, for the purposes of § 300aa-16(a)(2), to be "vaccine-related" the "first symptom or manifestation of onset or of the significant aggravation of such injury" cannot occur until the medical community at large objectively recognizes a link between the vaccine and the injury.

The government's arguments to the contrary are unpersuasive. First, HHS argues that "Congress chose to start the running of the statute before many petitioners would be able to identify, with reasonable certainty, the nature of the injury." *See Markovich*, 477 F.3d at 1358. However, as the preceding discussion demonstrates, the issue is not whether a petitioner subjectively recognizes an injury as vaccine-related, but rather whether the medical community at large objectively recognizes the injury as vaccine-related. Second, HHS argues that Dr. Cloer's position would essentially "eviscerate" the limitations period provided in the Vaccine Act for most non-Table injuries. HHS alleges that, in many non-Table cases, the first time an injury is causally associated with a vaccine is well after the petition has been filed. Be that as it may, the relevant inquiry for determining when the limitations period begins to run is generally this: when does the medical community at large recognize that a vaccine is linked to an injury? That the stat-

ute of limitations may start running later for certain non-Table injuries does not "eviscerate" the statue of limitations.

The dissenting opinion argues that our interpretation of "vaccine-related injury" creates a substantial new hurdle for petitioners alleging non-Table injuries, suggesting that a claim could not be brought until the medical community had recognized a link between the vaccine and the injury. The dissent assumes that the time at which the right to bring suit for a non-Table injury accrues and the time of commencement of the limitations period are the same. They are not. The usual rule is that the right to bring suit and the commencement of the limitations period is the same, *i.e.*, that the limitations period begins to run when the cause of action accrues. *Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 545 U.S. 409, 418-19 (2005). But this presumption does not exist where statutory language is to the contrary. *See id.*; *Dodd v. U.S.*, 545 U.S. 353, 360-61 (2005) (holding that the statutory language demonstrated that the limitations period and the petitioner's right to bring suit did not commence at the same time). Here, significantly, the statute relating to non-Table injuries uses quite different language to denote the commencement of the limitations period than it uses to describe the proof required to establish the vaccine injury. The statute of limitations subsection provides, "No petition may be filed . . . after the expiration of 36 months after the date of the occurrence of the *first symptom or manifestation of onset or the significant aggravation of such injury*," 42 U.S.C. § 300aa-16(a)(2) (emphasis added), whereas the non-Table proof of injury subsection provides, "A petition . . . shall contain . . . an affidavit, and

supporting documentation, demonstrating that the person who suffered such injury . . . sustained, or had significantly aggravated, any illness, disability, injury or condition . . . which was *caused* by a Vaccine referred to in subparagraph (A). . . . " 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) (emphasis added)., This difference in language is not inadvertent since in the statutory provisions relating to Table injuries, the right to bring suit depends on satisfying the "first symptom or manifestation" standard within the time period set forth in the Table.[1] Thus, for Table cases, which do not require causation, the "first symptom or manifestation" language is used in both the statute of limitations and proof of injury subsections. In contrast, for non-Table cases, the "first symptom or manifestation" language is only used in the statute of limitation subsection and the "cause[s]" language applies to the proof of injury subsection. This deliberate choice of different language shows that the time one can bring suit for a non-Table injury (and prevail)[2] is not the same as the time the limitations period begins. *See Dodd*, 454 U.S. at 361.

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[1] *See* § 300aa-11(c)(1)(C)(i) (" . . . sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the *first symptom or manifestation of the onset or of the significant aggravation of any such illness*, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table . . . . ") (emphasis added).

[2] § 300aa-11(c)(1) provides the requirements for a Vaccine Act petition. § 300aa-13(a)(1) states that compensation shall be awarded if the special master or court finds on the record as a whole that the petitioner has demonstrated by a preponderance of the evidence the matters required by § 300aa-11(c)(1). Thus, § 300aa-11(c)(1) lists the requirements for a successful petition at trial.

The dissenting opinion would require that the statute of limitations begin running even if there was no known medical association between a vaccine and an injury. A petitioner who suffered a hypothetical injury in Year 1 would be required to file a petition within three years even if no one in the medical community knew of the association between the vaccine and the injury until Year 5. The general purpose of a statute of limitations is that a person should be diligent in pursuing her claim but, in this situation, it would be impossible for a petitioner—even if perfectly diligent—to know that she needed to file a claim. And if such a petitioner did bring a claim for her injury, it would probably be denied as she likely would be unable to prove causation-in-fact. Thus, the statute of limitations cannot begin to run when there is no medically recognized link between the vaccine and the injury.

Moreover, starting the running of the statute of limitations at the exact moment a person could prevail on a causation-in-fact claim would be unworkable. Causation-in-fact may be proven by medical opinion, such as medical testimony. *See Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279 (Fed. Cir. 2005). Thus, a petitioner could be required to bring immediate suit simply because she theoretically might be able to find and hire a medical expert to testify to such a link. This depends on the possible ability of a petitioner to find a pioneering medical expert rather than the objective medical community standard. Also, at the time a claim under the Vaccine Act is filed, it is unclear whether a hired medical expert could, in fact, prove causation-in-fact because such a determination is not made until the special master or court conducts a hearing and makes a ruling. *See* § 300aa-13(a)(1)(A). This

necessarily constitutes a merits-based inquiry that should not preclude the filing of a claim.

Our decision does not conflict with *Brice v. Sec'y of Health & Human Servs.*, 240 F.3d 1367 (Fed. Cir. 2001), because our holding is based upon the proper interpretation of § 300aa-16(a)(2). We do not need to equitably toll the limitations period to save Cloer's complaint because § 300aa-16(a)(2) permits her claim since the limitations period, properly interpreted, never began. In addition, while Brice noted that Congress had intended that Vaccine Act claims be resolved "as expeditiously as possible," this statement was in the broader context of replacing a traditional tort system that "was inadequate to compensate many who were injured by vaccines." *See id.* at 1368-69. As this court stated in *Brice*, "Congress noted that opportunities of those injured by vaccines to seek redress under the traditional tort system were 'limited, time-consuming, [and] expensive,' and that for the injured, 'mounting expenses must be met.'" *Id.* at 1368 (quoting H.R. Rep. No. 99-908, at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347). Congress intended that awards under the Vaccine Act be made "quickly, easily, and with certainty and generosity." *Id.* at 1368-69 (quoting H.R. Rep. No. 99-908, at 3, *reprinted in* 1986 U.S.C.C.A.N. at 6344). Thus, generosity and reliability to petitioners were as much emphases of Congress as speed. The dissenting opinion, however, would not resolve Vaccine Act petitions generously or with certainty, given that one who is injured would be expected to predict whether there would be a medical linkage between a symptom and a vaccine by a pioneering expert within the next three years. Nor does it encourage expeditious resolution of the claims because a perfectly diligent person would still not know to file a claim any earlier than when

the medical community recognizes a link. Thus, Congress could not have intended to prevent petitioners in such a situation from filing claims.

The dissenting opinion also argues that the majority opinion is inconsistent with *Markovich v. Sec'y of Health & Human Servs.*, 477 F.3d 1353 (Fed. Cir. 2007). However, as discussed above, *Markovich* is factually distinguishable from the instant case and thus compelled a different result. In *Markovich*, there was no dispute that the petitioner suffered from seizures as a result of the administration of the vaccine. *Id.* at 1356. The first symptom that Ashlyn experienced, a rapid eye blinking episode, was not normal childhood behavior and would have at the very least raised the suspicions of medical professionals. *See id.* at 1360. The central dispute was whether the statute of limitations should be objective or subjective. *See id.* at 1356-57. The Markoviches argued that the standard should be subjective, based solely on the view of a particular parent. *Id.* at 1356. The government argued that the standard should be objective, based on the recognized standards of the medical community. *Id.* at 1357. We held that the standard necessarily focused on the recognized standards of the medical community and apply that same holding to the facts here.

Finally, the dissent points out that in *Wilkerson*, we stated that "[w]e do not read *Markovich* as requiring in each case a showing of the date on which the medical profession at large has such a recognition." Dissenting op. 9 (quoting *(Wilkerson v. Sec'y of Dep't of HHS*, 2010 WL 292661, at *3 (Fed. Cir. Jan. 27, 2001)). Consistent with *Wilkerson*, we do not suggest that general medical community recognition of a link is required in every case

in order for the statute of limitations to begin running. Where a claimant has received a medical opinion or medical knowledge that symptoms suggest a possible link between the vaccine and the injury, such notice will also suffice to trigger the statute of limitations.

When Dr. Cloer first experienced symptoms in 1997, the medical community at large did not recognize a link between MS and her vaccine. Dr. Meyer, a recognized expert in neurology, testified that he was unfamiliar with any causal link between MS and a vaccine. HHS's own brief also notes that "the medical community at large does not accept a causal association between the hepatitis B vaccine and multiple sclerosis." Appellant's Br. at 16 n.4. In addition, the Vaccine Injury Table does not list MS as a vaccine-related injury. *See* §§ 300aa-11(c)(1)(C)(ii), 300aa-14.

Based on the record before us, the earliest *any* member of the medical community alleged he recognized a link between MS and a vaccine was September 2004, when an article was published in *Neurology*. Thus, the medical community at large could not have objectively recognized Dr. Cloer's symptoms as a vaccine injury any earlier than September 2004, if then. *See Markovich*, 477 F.3d at 1360. Usually more than one study or article is required. So too, in this case, at the earliest, Dr. Cloer (a medical professional) was put on notice about the possibility of a connection between MS and the vaccine due to the September 2004 *Neurology* article. As her petition was filed within 36 months of that time, the petition is timely.

Because Dr. Cloer filed her Vaccine Program petition on September 16, 2005, less than 36 months after September 2004, her petition is not time barred.

CONCLUSION

For the reasons provided above, the judgment of the Court of Federal Claims is

REVERSED AND REMANDED

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2009-5052

MELISSA CLOER, M.D., PETITIONER-APPELLANT

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

Appeal from the United States Court of Federal Claims in 05-VV-1002, Judge Lawrence J. Block

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CLEVENGER, *Circuit Judge*, dissenting.

Multiple sclerosis ("MS") is a horrible disease. In many cases, the disease manifests itself slowly. A person can experience a symptom of MS in a passing manner; a mild symptom can come and go with no apparent lasting effect. Some medically-recognized symptoms of MS are common events for many people: fatigue, numbness, dizziness, weakness, impaired mobility. Such events arising after a hepatitis B vaccination may not hamper a person enough to cause a visit to a doctor, let alone persuade one to file a lawsuit, even though the symptoms could be identified by any competent doctor as symptoms of MS. Until severe and repetitive symptoms arise, a confirmed diagnosis of MS is difficult, and to this day, there is no medical consensus establishing a

causal association between the hepatitis B vaccine and MS.[1]

In the past, persons suffering symptoms of demyelinating diseases have filed non-Table petitions, seeking to establish the required causal link between the hepatitis B vaccine and their disease.[2] Such cases were filed within three years of the first occurrence of a symptom or manifestation of onset of the demyelinating disease and those petitioners may have been successful. Dr. Cloer's case, had it been timely, was not necessarily doomed to failure.

For petitioners suffering from non-Table injuries who fail to bring suit within three years of onset, the majority provides the best possible solution, especially with

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[1] *See Immunization Safety Review: Hepititis B Vaccine and Demyelinating Neurological Disorders* 1, 8 (Kathleen Stratton et al. eds., The National Academies Press 2002).

[2] Due to the large number of related non-Table petitions, the Office of Special Masters created a Hepatitis B-Neurological Demyelinating Omnibus Proceeding to determine if the hepatitis B vaccine can cause demyelinating diseases. In four paradigm cases, Special Masters found that petitioners successfully demonstrated a causal link between the hepatitis B vaccine and demyelinating diseases even though no such causal link was objectively recognized by the medical profession. *See Peugh v. Sec'y of Health and Human Servs.*, No. 99-638V, 2007 WL 1531666 (Fed. Cl. Spec. Mstr. May 8, 2007) (hepatitis B vaccine caused Guillain-Barre Syndrome); *Werderitsh v. Sec'y of Health and Human Servs.*, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006) (hepatitis B vaccine caused MS); *Gilbert v. Sec'y of Health and Human Servs.*, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006) (hepatitis B vaccine caused Guillain-Barre Syndrome and chronic inflammatory demyelinating polyneuropathy); *Stevens v. Sec'y of Health and Human Servs.*, No. 99-594, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006) (hepatitis B vaccine caused transverse myelitis).

regard to diseases that initially present with mild symptoms, such as MS. Under the majority's solution, the person suffering need not worry about the three-year statute of limitations in the Vaccine Act, unless there is consensus in the medical profession that the administered vaccine causes the adverse condition being experienced.[3] As there is no present medical consensus regarding almost all alleged non-Table injuries, injured persons can generally pick the time when they wish to bring their cases. For them, as for Dr. Cloer, the majority proposes that there is no applicable statute of limitations in the Vaccine Act.

As a matter of grace and perhaps public health policy, the majority has created a new statute of limitations for non-Table petitioners under the Vaccine Act. Neither I nor the majority have the slightest sense of whether this move is wise, but it is wrong as a matter of law, as I will now explain.

I

Dr. Melissa Cloer received her third and final hepatitis B vaccination on April 3, 1997. Before that time, she had no significant medical issues and enjoyed generally good health. About a month after her final vaccination, she began to experience numbness in her left forearm and hand. She also began to experience what she described as an "electric shock sensation" with "electric like sensations going down the center of her back to both feet with forward head flexion." This sensation is known as Lhermitte sign, long recognized by the medical profession as a common symptom of MS. *See Dor-*

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[3] This is the "general" rule created by the majority. The majority's exception to its general rule is discussed in Part VI, *infra*.

land's Illustrated Medical Dictionary 1700 (30th ed. 2003).[4]

In 1998, about a year after her final vaccination, Dr. Cloer sought treatment from Dr. Michael Andrew Meyer, an expert in the field of neurology with a specialty in MS. After an MRI examination, Dr. Meyer noted "probable early inactive non-progressive CNS [central nervous system] demyelination/MS," although he explained that her situation did not meet "formal diagnostic criteria for clinically definite MS." Even so, because the MRI revealed lesions on the white matter of her central nervous system, Dr. Meyer concluded that Dr. Cloer could have MS, Singular Sclerosis, Lyme Disease, and acute disseminating encephalomyelitis, along with other demyelinating processes. Before the Special Master, Dr. Meyer testified that "I think that the first MS related symptom was the [Lhermitte] phenomenon that she had in 1997."

On May 6, 1999, Dr. Cloer received a neurological examination from Dr. Ted Colapinto. Dr. Colapinto noted Dr. Cloer's medical history and recorded her complaints of numbness in her face, arms and legs, and her difficulty in walking. He concluded that Dr. Cloer's symptoms likely represented a demyelinating disease, commenting that "[Dr. Cloer] is having waxing and waning neurological symptoms in multiple areas of her body. I fear that this may likely represent demyelinating disease."

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[4] Lhermitte sign is defined as the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in MS but also in compression and other disorders of the cervical cord.

Notwithstanding the possibility that her vaccinations may have caused the symptoms of MS she displayed, Dr. Cloer did not file her petition for compensation for a vaccine injury until September 16, 2005, nearly two years after she received a definite diagnosis of MS in November 2003.[5]

Before the Chief Special Master, and then the Court of Federal Claims, Dr. Cloer did not challenge the uncontroverted evidence that she had suffered symptoms of MS, and likely the manifestation of onset of MS, recognizable as such by the medical profession, more than three years before the filing of her petition, thus time-barring her petition. Her primary argument to the Chief Special Master was that the statute of limitations should not begin to run until she received a "clinically definite" diagnosis of MS in 2003.

Relying on precedent of this court, the Chief Special Master rejected Dr. Cloer's theory and held that the statute of limitations begins to run on the occurrence of the first symptom or manifestation of onset of the injury which the petitioner alleges has resulted from the vaccination. The Chief Special Master discussed at length our decision in *Markovich v. Secretary of Health and*

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[5] As the majority notes, Dr. Cloer did not think there was a link between the hepatitis B vaccine and MS until she read an article in the September 2004 issue of *Neurology*. The article reported on a prospective study in France on the *possibility* of a causal connection between the hepatitis B vaccine and MS, referring to statistics from studies with "substantial methodologic limitations" showing an increased risk of MS after receipt of the hepatitis B vaccine. As the majority must concede, the prospective French study cannot constitute recognition by the medical community at large of a causal link between the hepatitis B vaccine and MS, and to suggest otherwise would be irresponsible. As noted above, the medical community at large denies any such link.

Human Services, 477 F.3d 1353 (Fed. Cir. 2007), quoting that "the terms of the Vaccine Act demonstrate that Congress intended the limitation period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." *Cloer v. Sec'y of Health & Human Servs.*, 2008 WL 2275574, *5 (Fed. Cl. Sp. Mstr. May 15, 2008). The Chief Special Master expressly dismissed Dr. Cloer's argument that a "clinically definite" diagnosis is required by *Markovich*:

> Petitioner misreads *Markovich*. The Court's holding was that for purposes of § 300aa-16(a)(2), "the first symptom or manifestation of onset" is the "first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." *Markovich*, 477 F.3d at 1360. There is no requirement that the *vaccine injury* be diagnosed.

Id. at *9 (emphasis in original).

Just as before the Chief Special Master, Dr. Cloer focused her argument at the Court of Federal Claims on her failure to receive a "clinically definite" diagnosis of MS until 2003. In addition, Dr. Cloer argued to the court that "because the first set of symptoms may be premature for a definitive diagnosis of a disease, it cannot itself constitute a 'vaccine injury.'"

The Court of Federal Claims rejected Dr. Cloer's theory that a "vaccine-related injury" cannot arise until the time when a causal link is shown between the claimed injury and the administration of a vaccine. Initially, the court noted that Dr. Cloer's statutory argument was essentially the same as her main argument requiring a

"clinically definite" diagnosis, but merely masked within an issue of defining the statutory term "vaccine-related injury." *Cloer v. Sec'y of Health and Human Servs.*, 85 Fed. Cl. 141, 149 (Fed. Cl. 2008). The court pointed out that deferring the statute of limitations until after recognition that the vaccine causes the alleged vaccine injury necessarily requires the alleged vaccine injury to be definitively diagnosed prior to the triggering of the statute. *Id.* The court ruled that Dr. Cloer's argument is "contrary to *Markovich*, which held that the limitation period begins to run at the first occurrence of a symptom even though an exact diagnosis may be impossible until some future date when more symptoms or medical data are forthcoming." *Id.* The court concluded that "[t]he Federal Circuit was very clear that diagnosis is not the test for the purposes of the statute of limitations." *Id.*

On appeal, Dr. Cloer renews her statutory interpretation theory. She maintains that no "vaccine-related injury" arises, for purposes of having a cause of action under the Vaccine Act, and for triggering its statute of limitations, until the medical community at large confirms a causal relationship between the injury and the administration of a vaccine. She cites this court's opinion in *Markovich* for support.

II

The Vaccine Act requires injured parties to file petitions within 36 months of the first symptom or manifestation of onset of the vaccine-related injury regardless of whether the petitioner is aware that the vaccine caused the injury. The "vaccine-related injury" is the injury that the petitioner alleges was caused by the vaccine.

In *Brice v. Secretary of Health and Human Services*, 240 F.3d 1367 (Fed. Cir. 2001), this court buttressed its conclusion that the Vaccine Act's statute of limitations permits no equitable tolling as follows:

> In addition, we note that the statute of limitations [under the Act] begins to run upon the first symptom or manifestation of the onset of injury, even if the petitioner would not have known at that time that the vaccine had caused an injury. It would have been quite odd for Congress to allow a limitations period to run in cases in which a petitioner has no reason to know that a vaccine recipient has suffered an injury, but to provide for equitable tolling when a petitioner is aware that a vaccine has caused an injury but has delayed in filing suit.

240 F.3d at 1373. *Brice* thus holds that the statute of limitations is triggered by the first symptom or manifestation of onset of the injury, even without a known connection between the symptom and the vaccine in question, and, moreover, holds that Congress intended this result. Further, we recognized in *Brice* that the statute of limitations is a condition on the waiver of sovereign immunity, and that the waiver cannot be broader than "that which Congress intended." *Id.* at 1370.

In *Markovich v. Secretary of Health and Human Services*, 477 F.3d 1353 (Fed. Cir. 2007), the plaintiff argued that eye blinking episodes were not enough to trigger the statute of limitations because "the eye blinking symptom could not reasonably alert the Markoviches that anything was wrong." 477 F.3d at 1357. Rejecting the argument that "the standard for statute of limitations purposes should be a subjective one, focusing on the particular view of a specific parent," *id.* at 1356, the

court instead found that "[a]n objective standard is consistent with the statutory requirement that the first symptom or manifestation of onset of the injury begins the running of the statute of limitations." *Id.* at 1360 (emphasis omitted). Thus, "the first symptom or manifestation of onset, for the purposes of § 300aa-16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." *Id.* The court in *Markovich* did not require an objectively recognized causal link between the vaccine and the injury. In a nutshell, the dispute in *Markovich* only concerned recognition of the symptom or manifestation as related to the injury claimed. We held that the statute of limitations begins to run upon the occurrence of the first symptom or manifestation recognized by the medical profession at large as a symptom or manifestation of the injury claimed, in this case, MS. We expressly rejected any notion that the statute of limitations would start to run when a petitioner had reason to believe the vaccine had caused the injury.

When *Brice* and *Markovich* are read in tandem, the law is clear. "[T]he Vaccine Act's statute of limitations must be strictly and narrowly construed because it is 'a condition on the waiver of sovereign immunity by the United States and courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended.'" *Markovich*, 477 F.3d at 1360 (quoting *Brice*, 240 F.3d at 1370). Thus, though the eye blinking in *Markovich* was "a symptom of a seizure disorder without any diagnosis," *id.* at 1357, it "was objectively recognized by the medical profession at large as constituting the first evidence of vaccine injury onset, i.e., the first symptom" of the seizure disorder suffered by the petitioner. *Id.* at 1360. It

did not matter that the eye blinking was not recognized as being causally linked to administration of a vaccine. *Id.* It only mattered that the eye blinking episodes were "connected to the injury of seizure disorder within ample time to have filed a timely claim." *Id.* at 1359. The court found the petition time-barred under section 300aa-16(a)(2). *Id.*

The court recently reaffirmed that *Markovich* keys to medical recognition of a link between the symptom and the injury claimed, not to medical recognition of a causal link between the injury and administration of a vaccine. *See Wilkerson v. Sec'y of Dept. of Health and Human Servs.*, 593 F.3d 1343, 1345-46 (Fed. Cir. 2010). In *Wilkerson*, the petitioner argued that the court's holding in *Markovich* that the statute of limitations triggers upon "the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large" requires a contemporaneous recognition in the medical community that the symptom is linked to the alleged vaccine injury. *Id.* at 1345. This, of course, is the same argument Dr. Cloer makes in this appeal. The court flatly rejected Wilkerson's argument and stated that:

> That statement in *Markovich*, however, was made to explain the court's rejection of a subjective standard for determining when the limitations period began to run based on the parent's perception of when that occurred, and adopting instead an objective standard based on the medical profession's recognition of when that occurred. We do not read *Markovich* as requiring in each case a showing of the date on which the medical profession at large had such a recognition.

Id. at 1345-46. Notwithstanding *Wilkerson*, the majority wants to interpret the same statement in *Markovich*

as holding that *Markovich* requires a contemporaneous recognition in the medical community of a link between the vaccine and the injury. To do so, the court simply ignores the holding in *Wilkerson* that "the Act's time for filing runs from 'the date of the occurrence of the first symptom or manifestation of onset,' not the date of its recognition." *Id.* at 1346.

Under the court's precedent, the Vaccine Act's statute of limitations starts running upon occurrence of the first symptom or manifestation of the alleged injury that is objectively recognized by the medical community as a symptom of the injury for which the petitioner seeks compensation. Putting this case into the correct *Markovich* analysis, the first objectively recognizable symptom of Dr. Cloer's MS by the medical profession at large was her Lhermitte sign in 1997. As correctly found by the Chief Special Master and the Court of Federal Claims, the statute of limitations began running on Dr. Cloer's Vaccine Program claim in 1997.

III

The Supreme Court has "repeatedly recognized" that "Congress generally drafts statutes of limitations to begin when the cause of action accrues." *Graham County Soil & Water Conservation Dist. v. United States*, 545 U.S. 409, 418 (2005). Indeed, the Supreme Court has refused to permit "the odd result" that a federal cause of action and statute of limitations arise at different times, "in the absence of any such indication in the statute." *Reiter v. Cooper*, 507 U.S. 258, 267 (1993). In *Graham County*, the Supreme Court was faced with a statutory scheme in which the relevant statute of limitations was subject to two plausible constructions. 545 U.S. at 419. The Supreme Court held that when differ-

ing but plausible constructions are possible, "we should adopt the construction that starts the time limit running when the cause of action [] accrues." *Id.*

In *Dodd v. United States*, decided the same day as *Graham County*, the Supreme Court was confronted with the one-year statute of limitations imposed by Congress on habeas corpus petitions based on rights newly recognized by Supreme Court decisions. 545 U.S. 353 (2005). The statutory language provided that the one-year period began to run on "the date on which the right asserted was initially recognized by the Supreme Court, if that right has been newly recognized by the Supreme Court and made retroactively applicable to cases on collateral review." *Id.* at 356-57 (quoting 28 U.S.C. § 2255 ¶ 6(3)). The Supreme Court held that the only natural reading of the statutory limitations period was for it to trigger upon the issuance of the decision initially recognizing the right in question. *Id.* at 357-58. Because the Supreme Court rarely determines retroactivity in its decisions initially recognizing a right, the Court acknowledged that when retroactivity is established more than one year after initial recognition of the right, the limitations period expires for petitioners before the cause of action accrues. *Id.* at 358-59. The Supreme Court held, however, that the general rule that a cause of action accrues at the same time the limitations period begins could be disregarded because Congress expressly and unambiguously provided for a different result. *Id.* at 359-60. The majority contends, wrongly I think, that Congress made a "deliberate choice" in the Vaccine Act to allow the cause of action for petitioners alleging non-Table injuries to accrue long before the statute of limitations begins to run, but to leave the general rule in force for petitioners alleging Table injuries.

IV

Under the Vaccine Act, there are two types of petitions, both of which are defined in the section of the Act titled "Petitions for Compensation." *See* 42 U.S.C. § 300aa-11. A person sustaining any "vaccine-related injury" must allege in their petition that they received a vaccine set forth in the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-11(c). For harms already recognized by the medical community, the Vaccine Act identifies the injuries commonly associated with each vaccine in the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-14. If the alleged injury is listed in the Vaccine Injury Table then the petitioner can file a Table petition; otherwise the petitioner must file a non-Table petition.

A petitioner filing a Table petition must allege that he sustained, or significantly aggravated, an illness, disability, injury or condition set forth in the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-11(c). The petitioner must also allege that the first symptom or manifestation of any such illness, disability, injury, or condition occurred within the time period after vaccine administration set forth in the Vaccine Injury Table. *Id.* These Table Injuries arise from an adequate consensus in the medical profession that a particular vaccine causes certain injuries. After a vaccine has been found often enough to have caused defined injuries with defined symptoms and manifestations occurring at defined times after vaccination, a Vaccine Injury Table entry is created. A petitioner seeking relief for any such injury no longer is required to allege that the vaccine caused the injury. A presumption of causation lies at the heart of Table Injury cases.

The Act also provides recovery for "non-Table" vaccine-related injuries. The required elements of a non-Table petition of course differ from the elements of a Table Injury petition. With regard to the "vaccine-related injury," a non-Table petitioner must allege that he "sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine. . . ." 42 U.S.C. § 300aa-11(c). A non-Table petitioner must aver and demonstrate that a vaccine has caused the vaccine-related injury for which he seeks compensation.

In sum, the Act creates a cause of action for persons suffering a "vaccine-related injury." *See* 42 U.S.C. § 300aa-11(a). The Act specifies the required contents of the petition for compensation. 42 U.S.C. § 300aa-11(c). For injuries listed in the Vaccine Injury Table the petitioner merely identifies his vaccine and alleged injury and benefits from a presumption of cause, but the Act leaves it to the non-Table petitioner to specify his own vaccine-related injury and to shoulder the burden of proof of causation. *Id.*

The Act contains a single statute of limitations for all persons suffering a "vaccine-related injury," regardless of whether they file Table or non-Table petitions. *See* 42 U.S.C. § 300aa-16(a)(2). The limitations statute applies "if a vaccine-related injury occurred as a result of the administration of [a] vaccine." *Id.* The phrase "occurred as a result of" necessarily refers to causation; presumptive causation in the instance of a Table Injury and alleged causation in non-Table petitions. In either instance, the petition must be filed within three years of "the date of the occurrence of the first symptom or man-

ifestation of onset" of the claimed vaccine-related injury. *Id.*

For both Table and non-Table petitioners, the "occurrence of the first symptom or manifestation of onset" is a date on a calendar when an event occurred. In Table cases, the symptoms or manifestations of onset, and the timeframe during which the symptoms or manifestations must have occurred, are defined with specificity in the Table. *See* 42 U.S.C. § 300aa-14. For non-Table cases, the first symptom or manifestation of onset, under our precedent, requires consensus in the medical community that the symptom or manifestation reflects the specific injury claimed to have been caused by the vaccine. *See Markovich*, 477 F.3d at 1360. The cause of action accrues, in both cases, upon the calendar date of the first symptom or manifestation, and the law requires the statute of limitations to begin to run on the same calendar date.

V

In light of the clear and binding precedent and the text of the Vaccine Act, the reader is surely asking how Dr. Cloer could possibly prevail. The answer lies in two steps taken by the majority. First the majority proposes: "Dr. Cloer interprets *Markovich* to mean that the medical community at large needs to recognize a link between the injury and the vaccine for the statute of limitations to begin running. We generally agree." *See* Maj. Op. at 6. As our recent decision in *Wilkerson* confirms, the majority and Dr. Cloer misread *Markovich*. As explained above, *Markovich* holds that the statute of limitations cannot run from just any symptom or manifestation; the triggering symptom or manifestation has to be one that the medical community at large recog-

nizes as a sign of the claimed injury. *Markovich* does not help the majority because, under our precedent, the statute of limitations begins to run before the medical profession at large concludes that the vaccine has caused the injury claimed; the lack of consensus exists in nearly every non-Table case ever brought before this court. In short, under our precedent, specifically *Brice*, *Markovich*, and *Wilkerson*, Dr. Cloer cannot prevail.

Second, the majority is forced to confront the general rule that a statute of limitations begins to run at the same time the cause of action arises because the term "vaccine-related injury" appears throughout the Vaccine Act. It appears in the provisions creating the cause of action and specifying the statute of limitations. A petitioner cannot file a petition seeking relief under the Act unless a "vaccine-related injury" has occurred, *see* 42 U.S.C. § 300aa-11(a)(1), and the statute of limitations begins to run three years after "the date of the occurrence of the first symptom or manifestation of onset . . . of such [vaccine-related] injury." *See* 42 U.S.C. § 300aa-16(a)(2). Because the majority defines a "vaccine-related injury" for purposes of the statute of limitations to mean "an injury that is causally connected by medical consensus to the vaccine in question," it necessarily understands that it can be criticized for erecting a bar that prevents petitioners (including Dr. Cloer) from filing causation-in-fact Vaccine Act petitions until such a time as there is consensus in the medical profession that the vaccine has caused the injury claimed. This would be so because if there is no "vaccine-related injury" without medical consensus on causation for statute of limitations purposes, *see* 42 U.S.C. § 300aa-16(a)(2), there can also be no "vaccine-related injury" for a cause

of action until the medical consensus is formed, *see* 42 U.S.C. § 300aa-11(a)(1).

The majority, however, appreciates the effect of the general rule, which would bar the public from filing non-Table petitions until after a medical consensus states that a vaccine causes a particular injury. To avoid the general rule, the majority separates the time of accrual of non-Table causes of action from the time on which the statute of limitations begins to run for such cases. In short, the majority dictates that the general rule which links accrual with initiation of the statute of limitations applies for Table Injury petitions, but does not apply to non-Table petitions. As a practical matter, there no longer will be any statute of limitations for non-Table petitions, as they by definition allege injuries that the Secretary has not added to the Vaccine Injury Table due to a lack of consensus on causation. As a legal mater, this ignores the plain language of the statute that creates a single cause of action for both Table and non-Table petitions. *See* 42 U.S.C. § 300aa-11(a)(1).

The majority seeks to justify its bifurcation by pointing out that, for Table petitions, the requirements include pleading the occurrence of a first symptom or manifestation of a defined vaccine injury within the Table-specified time, and the Vaccine Act statute of limitations uses the same language to trigger the running of the three-year period for bringing Vaccine Program claims. The majority then points out that the requirements for non-Table petitions, though arising under the same cause of action, do not mention "first symptom or manifestation" and instead require a petitioner to plead that the vaccine caused the claimed injury. This "deliberate choice" of different language for the contents of

Table and non-Table petitions, according to the majority, proves beyond question that Congress intended to produce the "odd result" that for non-Table petitioners the cause of action can arise before the statute of limitations begins to run, and that, in fact, there may not even be a statute of limitations for most non-Table cases as the alleged injuries may never be objectively recognized as caused by the vaccine.

Notably, there is no evidence whatsoever in the legislative history of the Act that Congress made a "deliberate choice" of different language in the petition requirements in order to reject the normal rule that a cause of action arises at the same time the statute of limitations begins to run. The difference in language is required because the Vaccine Injury Table only contains injuries that the medical community has concluded are likely to be caused by certain vaccines. Thus, petitioners alleging a Table Injury must comply with the requirements of the Vaccine Injury Table, and the statute of limitations runs from the defined time of the relevant symptom or manifestation listed in the Table. *See* 42 U.S.C. § 300aa-14. For non-Table injuries, there are no such medically agreed-upon symptoms or manifestations that appear within a defined timeframe after administration of the vaccine. Because Congress provided a single limitations period to run for all vaccine cases from the date of the first symptom or manifestation, *see* 42 U.S.C. § 300aa-16(a)(2), Congress left it to petitioners alleging non-Table injuries to prove when their first symptom or manifestation of onset occurred. Our case law has defined that date to require that the symptom or manifestation of onset be recognized by the medical profession as a symptom or manifestation of the injury claimed.

The Vaccine Act does not express a "deliberate choice" by Congress to enforce the statute of limitations for Table Injury petitioners, but indefinitely suspend or eliminate it for non-Table petitioners. Nor does the Vaccine Act present more than one interpretation of how its single statute of limitations works. There is simply no statutory support for the majority's reasoning that the single statute of limitations in the Vaccine Act somehow applies differently to petitioners depending on whether they allege Table or non-Table injuries.

The majority is plainly wrong to read the same statutory language to have two quite different meanings. Only by refusal to abide by our precedent (*Markovich* and *Wilkerson*), by misapplication of Supreme Court law (*Dodd*), and by creating two definitions for a single statutory term, can the majority save Dr. Cloer from the expired statute of limitations.

VI

The majority conditions its "general rule" (that the statute of limitations does not run until a medical consensus recognizes a causal link between a vaccine and an injury) with what seems to be an afterthought. The condition is that, even if there is no medical consensus on causation, the statute of limitations may begin to run if a person has reason to believe that a vaccine caused the injury claimed.

Here, the majority stubs its toe over *Markovich* for the second time. If *Markovich* makes nothing else clear, it surely teaches that subjective considerations have no place in determining when the statute of limitations in the Vaccine Act begins to run.

The majority's add-on test is full of subjective issues: what did the would-be petitioner understand, and from where, and what was the basis for the supposed linking information, and would a reasonable person have so interpreted the information when other similarly situated persons understood the information differently? The only objective thing about the add-on test is that it triggers the statute of limitations on the date when the "medical information" is received. But under *Markovich*, the trigger date has to be the date upon which a symptom or manifestation occurred. Under the add-on test, *Markovich*'s trigger is eviscerated.

Further, the add-on test ignores (and overrides) the plain holding in *Brice* that the statute of limitations begins to run before a petitioner suspects a causal link between a vaccine and the injury claimed. Instead, the majority's add-on test triggers the statute of limitations on the date that the petitioner first suspects a causal link.

Enough said. I need not belabor the wrongness of the majority's bewildering exception test for starting the statute of limitation on non-Table petitioners. I might add, as a possible explanatory note to the readers, that Ms. Cloer did not present the majority's exception theory below, nor in the briefs or at oral argument here. Ms. Cloer argued only that the statute should not begin to run until the medical community arrived at a consensus causally linking the hepatitis B vaccine to MS. The illogic of her position and the chaos it would cause for bringing non-Table cases are evident, given the rule that a cause of action accrues and the statute of limitations begins to run at the same time. The majority overcomes Dr. Cloer's flawed argument first by refusing to follow

Brice, *Markovich* and *Wilkerson* and by misapplying *Dodd*, and finally by trying to limit the damage done by its general rule by hiving onto it a subjective condition.

VII

The law of this circuit is clear: the statute of limitations in the Vaccine Program begins to run upon the first symptom or manifestation of a claimed vaccine injury, where that symptom or manifestation is recognized by the medical profession as a symptom or manifestation of the injury claimed. Requiring consensus in the medical profession that there is a causal link between the vaccine in question and the non-Table injury claimed has no place in the Vaccine Act. Such consensus arises, inter alia, from successfully litigated non-Table petitions.

A rule that the statute of limitations cannot begin to run for petitioners alleging non-Table injuries until medical consensus of a causal link arises creates havoc with the public's opportunity to file non-Table cases. Congress did not make a deliberate choice to bifurcate the Vaccine Act's non-Table petition requirements from the statute of limitations, and Congress surely could not have intended to so limit the availability of non-Table injury petitions as with the majority's definition of "vaccine-related injury."

To be correct, the court should define "vaccine-related injury" in the Vaccine Act to mean "the injury claimed by a petitioner to have been caused by administration of a vaccine." This matches the plain language of the Act and the general rule requiring Vaccine Program causes of action to accrue on the same date that the statute of limitations begins to run. This date is defined as the date of occurrence of the first symptom or manifestation of onset of the injury claimed, recognized as such

by the medical profession. Under the correct test, Dr. Cloer's petition is time-barred.

For the foregoing reasons, I would affirm, and thus respectfully dissent.

APPENDIX E

UNITED STATES COURT OF FEDERAL CLAIMS

No. 05-1002 V

MELISSA CLOER, M.D., PETITIONER

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT

Filed Under Seal: Nov. 25, 2008

OPINION AND ORDER

BLOCK, Judge.

I. INTRODUCTION

The case before the court is a review of the Chief Special Master Golkiewicz's decision dismissing petitioner's claim for compensation under the National Vaccine Injury Compensation Program ("the Program" or "the Vaccine Act"),[1] 42 U.S.C. §§ 300aa-10 to -34. *Cloer v. Sec'y of the Dep't of Health & Human Servs.* ("*Cloer I*"), 2008 WL 2275574 (Sp. Mstr. Fed. Cl. May 15, 2008). The

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[1] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 *et seq.* (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act").

issue in this case surrounds the proper interpretation of the Vaccine Act's limitations period. Section 300aa-16(a)(2) of Title 42 bars all petitions seeking compensation for any vaccine injury from an on-Table vaccine "after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." The issue facing this court is whether the limitations period commences according to a subjective test of when a petitioner discovered the existence of the disease or malady, or according to the more restrictive objective test of when the earlier of the first particular symptom of a vaccine injury occurred or the onset of that injury manifested.

The petitioner, Dr. Melissa Cloer, had received a series of three Hepatitis B ("Hep-B") *vaccinations* starting in fall of 1996, after which, in 1997, she began to experience neurological symptoms indicating a demyelinating[2] disease. *Cloer I* at *1-*3. Following a May 1998 MRI revealing lesions on the white matter of her central nervous system, Dr. Cloer received differential diagnoses that included Multiple Sclerosis,[3] Singular Sclerosis,

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[2] "Myelin is a collection of lipid fats and proteins that sheaths the long extensions of nerve cells (neurons) called axons. Myelin considerably increases the speed that nerve signals (impulses) move down the axons." Multiple Sclerosis Encyclopaedia, *Myelin*, http://www.mult-sclerosis.org/myelin.html. Thus, a demyelinating disease is one in which lesions appear in the myelin sheaths surrounding the axons.

[3] See DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1669 (30th ed.2003) (observing that the etiology-also known as "causation"—of MS is unknown). MS is:

> a disease in which there are foci of demyelination of various sizes throughout the white matter of the central nervous system, sometimes extending into the gray matter. Typically, the symptoms of

Lyme Disease, and acute disseminating encephalomyelitis, along with other demyelinating processes. *Id.* Over the next several years, Dr. Cloer suffered other episodic symptoms consistent with a demyelinating disease. *See id.* at *2-*4. On November 26, 2003, Dr. Cloer received a "provisional" diagnosis of MS by her treating neurologist, Dr. Wood. *Id.* at *2.

But it was not until September 16, 2005, that Dr. Cloer filed a petition pursuant to the Program, alleging that she "had sustained and/or significantly aggravated Multiple Sclerosis as a result of receiving Hep-B immunizations in 1996 and 1997." *Id.* at *1. After receiving evidence, holding a hearing, and receiving post-hearing briefs from both parties, Chief Special Master Golkiewicz dismissed Dr. Cloer's petition because she failed to file within three years of the first symptom or manifestation of onset of her claimed vaccine injury, which occurred in 1997. *Id.* at *8-*10. Accordingly, the Chief Special Master applied the more restrictive construction of the Vaccine Act's limitations period. *Id.* at *4-*9. The Chief Special Master rejected petitioner's contention that the more lenient subjective view of the limitations period should control. *Id.* at *8-*9. Petitioner had argued that because it was not until November, 2003, that Dr. Cloer received even a provisional diagnosis of MS, not only would it be wholly unfair to apply the more restrictive objective limitations period, it would also vio-

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lesions of the white matter are weakness, incoordination, paresthesias, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that *the term multiple also refers to remissions and relapses that occur over a period of many years.* Four types are recognized, based on the course of the disease: relapsing remitting, secondary progressive, primary progressive, and progressive relapsing.

late Fifth Amendment constitutional precepts of equal protection and due process. *See id.* at *9 n.10.

On June 16, 2008, petitioner filed in this court a Motion for Review of the Chief Special Master's decision. Pet.'s Mem. 34. Thus, petitioner asks this court to reverse the Chief Special Master's May 15, 2008 decision dismissing her petition based on the restrictive view of the Program's three-year statute of limitations. Pet.'s Mem. 1. Upon review, for the reasons stated below, the court holds that the Chief Special Master applied the correct legal standard in determining that Dr. Cloer's petition was untimely. Furthermore, as also explained below, the court rejects petitioner's constitutional arguments.

II. BACKGROUND[4]

A. Dr. Cloer's Medical History

Dr. Cloer was born on January 22, 1968. Prior to exhibiting symptoms of a demyelinating disease, Dr. Cloer had no significant medical issues and enjoyed generally good health. She began the series of Hep-B vaccinations on September 3, 1996, and received the second vaccination on November 11, 1996. Thereafter, Dr. Cloer reported that after these two vaccinations, she experienced some numbness and tingling. Dr. Cloer received her third and final Hep-B vaccination on April 3, 1997.

About a month after her final vaccination, Dr. Cloer began to experience numbness in her left forearm and hand. Dr. Cloer also began to experience what she des-

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[4] The facts, drawn from the pleadings and the Chief Special Master's decision in *Cloer I*, are undisputed, although, as the Chief Special Master characterized it, "the significance of the facts is the consequence of the dispute." *Cloer I* at *3.

cribed as an "electric shock sensation," with "electric like sensations going down the center of her back to both feet with forward head flexion." This sensation is known as Lhermitte sign, a common symptom of MS.[5]

Concerned about these symptoms, Dr. Cloer went to her family physician, who prescribed Motrin. This initial set of symptoms mostly disappeared over the next few months. In 1998, about a year after receiving her final vaccination, Dr. Cloer sought treatment from Dr. Michael Andrew Meyer, an expert in the field of neurology with a specialty in MS. Dr. Meyer ordered an MRI, and based on the results indicating white matter lesion, concluded that Dr. Cloer could have MS, lyme disease, acute disseminating encephalomyelitis, or other demyelinating processes. Dr. Meyer noted "[p]robable early inactive non-progressive CNS [central nervous system] demyelination/MS," even though he had not yet *diagnosed* Dr. Cloer with MS. Dr. Meyer later recalled that during the period he treated Dr. Cloer, "[t]here had been no manifestation of onset of clinically definite multiple sclerosis." *Id.* at *3 (quoting Dr. Meyer's affidavit (emphasis added)). Dr. Meyer explained in his affidavit to the Chief Special Master that Dr. Cloer did not meet "*formal diagnostic criteria* for *clinically definite* MS" because Dr. Cloer's "singular demyelinating change

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[5] Also known as Lhermitte's sign or Lhermitte's phenomenon. Lhermitte sign is defined as:

> the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; *seen mainly in multiple sclerosis* but also in compression and other disorders of the cervical cord.
>
> DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1700 (30th ed. 2003) (emphasis added).

could have remained a clinically isolated event with no sequela." *Id.* (quoting Dr. Meyer's affidavit (emphases added)).

On May 6, 1999, Dr. Cloer received a neurological examination from Dr. Ted Colapinto. Dr. Colapinto noted Dr. Cloer's medical history, described above, and recorded her complaints of numbness in her face, arms, and legs, and her difficulty in walking. Dr. Colapinto noted that Dr. Cloer's symptoms likely represented a demyelinating disease. During a follow-up visit on June 3, 1999, Dr. Colapinto observed improvement in Dr. Cloer's lower extremities, though she still had weakness and numbness in her right leg. At this time, Dr. Colapinto again expressed his concern that Dr. Cloer had a demyelinating disease.

Dr. Kevin Wood, who evaluated Dr. Cloer on November 26, 2003, recorded that Dr. Cloer believed that her symptoms began in 1997. Discussing the patient history, Dr. Wood noted that Dr. Cloer also had episodes of variable weakness and numbness of her legs, and an episode of numbness of her right face. Dr. Wood's notes also record that Dr. Cloer's 1998 MRI was reportedly suspicious for demyelinating areas, though her spinal cord MRIs were unremarkable. After examining Dr. Cloer's medical history and 1998 MRIs, Dr. Wood gave her a "provisional diagnosis" of MS. Dr. James P. Metcalf, who evaluated Dr. Cloer for Social Security Disability in 2004, observed that she began to show symptoms consistent with MS in 1997; though these symptoms waxed and waned until fall of 2003, when Dr. Cloer began to manifest "full blown" MS. *Id.* at *2.

B. *Cloer I*

Dr. Cloer filed her petition for compensation for a vaccine injury on September 16, 2005. Chief Special Master Golkiewicz received multiple pleadings and affidavits concerning whether Dr. Cloer's petition was timely under the Program. *Cloer I* at *1. Chief Special Master Golkiewicz also held a telephonic hearing to elicit testimony from Dr. Meyer, after which both parties filed additional post-hearing briefs. *Id.* In evaluating Dr. Cloer's petition for compensation for a vaccine injury under the Program, the Chief Special Master provided an extensive discussion of Dr. Cloer's medical history and the affidavits of her physicians.

Dr. Cloer's argument made to the Chief Special Master is as follows: although Dr. Cloer experienced Lhermitte sign, a symptom of MS, in 1997, and each doctor who saw Dr. Cloer for her demyelinating disease traced its first symptoms back to her Lhermitte sign in 1997, Dr. Cloer did not receive a *clinically definite diagnosis* of MS prior to 2003 and neither she nor her physicians were aware of a potential link between MS and vaccinations until after 2003. *Cloer I* at *1-*7. To be sure, Dr. Cloer argued that, based on the knowledge available at that time to the medical community, a diagnosis of MS due to a vaccine injury must be predicated on a manifestation of MS that lasted for at least six months. *Id.* at *9-*10. Thus, Dr. Cloer argues that she could not have petitioned for compensation because no member of the medical community at large would have linked her demyelinating disease problems to the Hep-B vaccinations until after 2003, and as such, her petition was timely. In essence, Dr. Cloer was asking the Chief Special Master to apply the more lenient subjective stat-

ute of limitations period of *Setnes v. United States*, 57 Fed. Cl. 175, 181 (2003) (holding that limitations period begins to run only when subtle symptoms of injury become clearly apparent and the onset of the manifestation of the disease can be diagnosed by a "treating physician").

In rejecting Dr. Cloer's argument, the Chief Special Master relied on the Federal Circuit opinion in *Markovich v. Sec'y of Health & Human Servs.*, 477 F.3d 1353 (2007), in applying the restrictive view of the limitation's period of the Vaccine Act. The Chief Special Master observed that in *Markovich*, the Federal Circuit interpreted the Vaccine Act's limitations period to commence on the date the first symptom or manifestation of onset occurs, even though that indication may well be "before many petitioners would be able to recognize with reasonable certainty the nature of the injury." *Id.* at 1357 (quoting *Markovich*). The Chief Special Master also noted that this view is supported by the Federal Circuit's recognition of the disjunctive test in § 16(a)(2) that emphasized the distinction between a symptom and a manifestation of onset.[6] *Id.*

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[6] The court stressed that the words "symptom" and "manifestation of onset" are in the disjunctive as used in the Act and that the words have different meanings. Thus, symptom "may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury," whereas a manifestation of onset "is more self-evident of an injury and may include significant symptoms that clearly evidence an injury." Accordingly, the court found that the Act's statutory standard of first symptom or manifestation of onset could include subtle symptoms that a petitioner would recognize "only with the benefit of hindsight, after a doctor makes a definitive diagnosis of the injury" and would be "recognizable to the medical profession at large but not neces-

In reviewing Dr. Cloer's medical history and the affidavits of her doctors, the Chief Special Master concluded, based on the affidavits of Dr. Cloer and her doctors, that the first manifestation of MS was the Lhermitte sign-the "electric shock sensation" that she experienced in 1997, *Id.* at *6-*8. Moreover, The Chief Special Master observed that even Dr. Meyer, Dr. Cloer's expert and the neurologist who treated Dr. Cloer in 1998, considered in retrospect that the first Lhermitte sign was her first symptom of MS. *Id.* at *9.

Accordingly, based on § 16(a)(2) of the Vaccine Act as informed by *Markovich*, the Chief Special Master interpreted the statute of limitations to trigger on the first symptom or manifestation of onset of MS in 1997, rather than adopt the more lenient view of the limitations period endorsed in *Setnes*—when the petitioner received her definitive diagnosis of the disease in 2003. *Id.* The Chief Special Master ultimately concluded that Dr. Cloer's petition, filed in 2005, was well outside the statute of limitations, which ended in 2000. *Id.* at *7-*8. Thus, Chief Special Master Golkiewicz dismissed Dr. Cloer's petition as barred by the Vaccine Act's three-year statute of limitations.

Finally, as to the constitutional arguments, the Chief Special Master noted in passing that petitioner had raised certain constitutional objections, which respondent vigorously opposed. *See Cloer I* at *9 n.10. Nevertheless, the Chief Special Master rejected these contentions without much comment because they were "not well-developed" and because similar or the same provisions were "analyzed and found to pass constitutional

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sarily to the parent." *Cloer I* at *5 (quoting *Markovich*) (internal citations omitted).

scrutiny" in *Leuz v. Secretary of HHS*, 63 Fed. Cl. 602 (2005). *Id.*

III. DISCUSSION

Section 12(e)(1) of the Vaccine Act establishes this court's jurisdiction to review decisions of a Special Master upon a properly filed motion for review. 42 U.S.C. § 300aa-12(e)(1); *see also* Vaccine Rule 23; *Phillips v. Sec'y of the Dep't of Health & Human Servs.*, 988 F.2d 111, 112 (Fed. C. 1993). This court may embark on one of three courses of action when reviewing a special master's decision in a vaccine case. *Rupert v. Sec'y of Dep't of Health & Human Servs.*, 55 Fed. Cl. 293, 297 (2003). This court may:

> (A) uphold the findings of fact and conclusions of law of the Special Master and sustain the Special Master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the Special Master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the Special Master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2)(A)-(C); *see also* Vaccine Rules 27, 36(b).

This court, moreover, should apply a different standard depending on what aspect of the Special Master's decision is under review.

> These standards vary in application as well as in degree of deference. Each standard applies to a differ-

> ent aspect of the judgment. Fact findings are reviewed by [the Federal Circuit], as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard.

Saunders v. Sec'y of Dep't of Health & Human Servs., 25 F.3d 1031, 1034 (Fed. Cir. 1994) (*quoting Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 n.10); *see also Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1277 (Fed. Cir. 2005) ("Under the Vaccine Act, the [United States] Court of Federal Claims reviews the special master's decision to determine if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." (internal quotations omitted)). The practical effect of this structure is to give the Special Master's determinations decisional effect, and to place this court in the role of a reviewing court. *Munn*, 970 F.2d at 869.

Clearly, the "not in accordance with law" standard is applicable in the case at bar because the primary dispute-interpretation and application of the appropriate limitations period-is a pure legal issue. *See Hines v. Sec'y Dep't of Health & Human Servs.*, 940 F.2d 1518, 1527 (Fed. Cir. 1991). And so are the constitutional claims attacking the Vaccine Act's limitation period. *See Leuz*, 63 Fed. Cl. at 607-12; *Blackmon v. American Home Prods.*, 328 F. Supp. 2d 647, 655-57 (S.D. Tex. 2004). Moreover, the petitioner also asserts an ancillary claim predicated on the arbitrary and capricious standard.

The court's inquiry in this regard must focus on whether the Chief Special Master examined the "relevant data" and articulated a "'satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" *See Hines*, 940 F.2d at 1527 (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983) (applying a similar standard of review for agency rulemaking under the Administrative Procedure Act)); *see also Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, 91 S. Ct. 814, 28 L. Ed. 2d 136 (1971) (The "arbitrary and capricious" determination involves a "consideration of the relevant factors and whether there has been a clear error of judgment."). The scope of review under this standard is highly deferential and precludes this court from substituting its own judgment for that of the Special Master. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43, 103 S. Ct. 2856 (*citing Bowman Transp. Inc. v. Arkansas-Best Freight System*, 419 U.S. at 286, 95 S. Ct. 438, 42 L. Ed. 2d 447 (1973)).

To be sure, this court must even "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Id.* (internal citations omitted); *Hines*, 940 F.2d at 1527 ("If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate."). Furthermore, the Act makes clear that this court "is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." *Hodges v. Sec'y of the Dep't of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). Indeed,

"[t]his is a standard well understood to be the most deferential possible." *Munn*, 970 F.2d at 870. Thus, the petitioner has a difficult row to hoe.

A. Was *Cloer I* "in accordance with law?"

With these standards in mind, the court turns to the two legal issues proffered by petitioner, the proper construction of the 36-month limitations period found in 42 U.S.C. § 300aa-16(a)(2), and the constitutionality of that section. Preliminarily, it should be noted that the statute of limitations issue goes to the heart of the jurisdiction of this court. This is so because the limitations period in the Vaccine Act "'is a condition on the waiver of sovereign immunity by the United States,' and courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended.'" *Brice v. Sec'y of Health & Human Servs.*, 240 F.3d 1367, 1370 (Fed. Cir. 2001) (quoting *Stone Container Corp. v. United States*, 229 F.3d 1345, 1352 (Fed. Cir. 2000)). Consequently, absent such congressional consent, this court lacks jurisdiction to grant relief. *See, e.g., United States v. Testan*, 424 U.S. 392, 399, 96 S. Ct. 948, 47 L. Ed. 2d 114 (1976); *United States v. Sherwood*, 312 U.S. 584, 61 S. Ct. 767, 85 L. Ed. 1058 (1941). It is also beyond doubt that waiver of sovereign immunity must be strictly construed. *See United States v. Mitchell*, 445 U.S. 535, 538, 100 S. Ct. 1349, 63 L. Ed. 2d 607 (1980); *Markovich*, 477 F.3d at 1360 (observing that the Vaccine Act's limitation period must be "strictly and narrowly construed because it is a condition on the waiver of sovereign immunity by the United States"). Thus, it is critical for this court to construe the relevant statute of limitations properly.

Accordingly, the issue presented to this court is whether the Chief Special Master correctly construed the limitations period of 42 U.S.C. § 300aa-16(a)(2). It is worth repeating that, by its terms, it bars all petitions seeking compensation for any vaccine injury from an on-Table vaccine "after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." The Hepatitis-B vaccine, the alleged culprit in this case, is indeed an "on-Table" vaccine. 42 U.S.C. § 300aa-14.[7] Section 300aa-16(a)(2) was therefore the proper limitations period to apply in this case. There are several cases that address this provision and clarify its construction, although one is contrary to the other two.

The first piece of the puzzle is *Brice*, where the Federal Circuit held that equitable tolling does not apply to the Vaccine Act's statute of limitations, 42 U.S.C. § 300aa-16(a)(2). 240 F.3d at 1372-74. In so holding, the Federal Circuit noted that this statute of limitations "begins to run upon the first symptom or manifestation of the onset of injury, *even if the petitioner reasonably would not have known at that time that the vaccine had caused an injury.*" *Id.* at 1373 (emphasis added). The *Brice* court apparently rejected the view (enunciated, as explained above, by petitioner in this court) that the limitations period begins only when a sufferer has reason to believe the vaccine caused the injury. To be sure, in explaining why this restrictive construction of the limitations provision buttressed the belief that the doctrine

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[7] *See* HRSA-National Vaccine Injury Compensation Program, *http://www.hrsa.gov/Vaccinecompensation/table.htm* (listing "VIII. Hepatitis B antigen-containing vaccines" on the Table).

of equitable tolling does not apply to § 300aa-16(a)(2), the court observed that it would be "quite odd for Congress to allow a limitations period to run in cases in which a petitioner has no reason to know that a vaccine recipient has suffered an injury, but to provide for equitable tolling when a petitioner is aware that a vaccine has caused an injury but has delayed in filing suit." *Id.* The issue of how strict is *Brice*'s restrictive view of the Vaccine Act's limitations period was addressed by the Court of Federal Claims in *Setnes v. United States*, 57 Fed. Cl. 175 (2003).

In reviewing a claim alleging that the vaccine recipient suffered the injury of an autism spectrum disorder, the Court of Federal Claims in *Setnes* took a broad view of the Vaccine Act's statute of limitations. (It is thus the odd-man out in this set of cases.) The Setneses had argued that the 36-month statute of limitations should date from July 16, 1999, when AJ's pediatrician, for the first time, found that AJ was not meeting "*medically appropriate* development guidelines." *Id.* at 179 (emphasis in original). Specifically, the Setneses maintained that because of its unique nature, "there can be no 'manifestation of onset' [for autism spectrum disorder] until such time as the medical and psychological professionals verify through reliable medical and psychological means that a constellation of behaviors presented in a specific child meet [its] criteria." *Id.* In response, the government, taking the more restrictive view, asserted that the plain language of the statute of limitations triggers only on "the occurrence of the first symptom" of the vaccine injury. *See id.* at 180.

In rejecting the government's restrictive view of the limitations period, the court concluded, based on expert

evidence, that "the beginning stage of autism cannot be reduced to a single, identifiable symptom . . . . [m]any of the initial symptoms are subtle and can easily be confused with typical childhood behavior." *Id.* The *Setnes* court determined that autism was a special case, "as distinguished from other medical conditions," because "there is no clear start to the injury." *Id.* Moreover, the court interpreted the "first symptom" and the "manifestation of onset" in the statute of limitations to have different meanings, rejecting the government's contention that the "onset" was determined by the first symptom. *See id.* Significantly, the court construed the limitations provision's term "manifestation of onset" to mean that the resulting disease must be "manifest," i.e., evident at the time, to trigger the statute of limitations. *Id.* at 180 (citing BLACK'S LAW DICTIONARY 867 (5th ed. 1979)). Thus, to the court, for diseases that develop "insidiously over time" in which the initial symptoms are not readily connected to any injury or disorder, the limitations period begins to run only when the manifestation of onset of a particular recognizable injury becomes evident. *See id.* The *Setnes* court concluded that because the special master improperly relied upon retrospective observations as to symptoms rather than contemporaneous medical conclusions as to the manifestation of the specific disease, the special master's decision was reversed and remanded. *Id.* at 180-81.

However, the validity of *Setnes* was made doubtful by the Federal Circuit in *Markovich*. Relying on *Setnes*, the Markoviches urged the Federal Circuit to interpret the Vaccine Act's statute of limitations to embody the more lenient subjective standard commencing only when the petitioner knew that an injury or symptom had occurred. *Markovich*, 477 F.3d at 1356. In affirming the

Court of Federal Claims, the Federal Circuit emphasized that the Vaccine Act's statute of limitations is disjunctive, and thus is triggered by *the earlier* of the first symptom of a vaccine injury or the manifestation of its onset. *See id.* at 1357-58. The court further distinguished between a "symptom" and "a manifestation of onset," giving semantic effect to the statute of limitations' syntactic distinction. *Id.* at 1358. The court explained that:

> [a] symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury. A manifestation of onset is more self-evident of an injury and may include significant symptoms that clearly evidence an injury.

Id. Significantly, the *Markovich* court criticized the *Setnes* rationale as problematic because it "effectively reads the Vaccine Act as if the statute of limitations were not triggered until there was appreciable evidence shoring a symptom *and* manifestation of the injury," in contrast to the clearly disjunctive language in the text. *Id.* (emphasis in original). The Federal Circuit also criticized *Setnes* for suggesting that a "subtle symptom or manifestation of the onset of the injury . . . that would be recognizable to the medical profession at large but not to the parent, would not be sufficient to trigger" the statute of limitations. *Id.* Instead, the Federal Circuit cited *Brice* for support, emphasizing that the Federal Circuit has consistently interpreted the Vaccine Act's statute of limitations to be triggered even on "subtle symptoms or manifestations of onset of the injury." *Id.*

Turning to the case at bar, what is fatal to petitioner's cause is that despite protests to the contrary, petitioner relies for support almost exclusively on *Setnes*. Thus, petitioner contends that her petition was timely within the statute of limitations because she only received a "clinically definite" diagnosis of MS in 2003, less than 36 months before filing her petition for compensation in 2005. Pet.'s Mem. 2, 15-21. Petitioner focuses on the medical criteria for *diagnosing* MS and the practical difficulties in doing so given the vagaries of the disease (which is a good application of the holding in *Setnes*), yet astonishingly claims that it is *Markovich* and § 300aa-16(a)(2) that requires that a doctor definitively connect the first symptom to a particular disease before the statute of limitations begins to run. *See, e.g.*, Pet.'s Mem. 3 (referring to "diagnosis or manifestation of onset of *Multiple Sclerosis*" (emphasis added)), 4 & n.2 (discussing criteria for diagnosing MS and how petitioner did not meet these diagnostic criteria), 8-9 (discussing Dr. Meyer's affidavit that he could not diagnose petitioner with clinically definite MS in 1998). According to petitioner, because she did not receive a definitive diagnosis of MS until 2003, and there was no reason for the medical community to suspect a vaccine link to MS until 2004, she could not have had a symptom or manifested the onset of MS as judged by the medical community at large. *Id.* at 11-14. In other words, petitioner is arguing for this court to apply the holding of *Setnes*, which is of questionable validity and not binding upon this court, rather than the valid binding precedent of *Markovich*.

Similarly, this court must reject petitioner's contention that the Chief Special Master's dismissal was legally erroneous because he relied on an idiosyncratic

definition of a "vaccine injury." This argument dresses the *Setnes* wolf in sheep's attire. Once again, petitioner argues that a "vaccine injury," the *sine qua non* for recovery under the Vaccine Act, by definition, cannot be based on the first occurrence of a symptom but is instead contingent on a physician's ultimate diagnosis of a disease based on a particular set of symptoms. Pet.'s Mem. 15-16. In other words, because the first set of symptoms may be premature for a definitive diagnosis of a disease, it cannot itself constitute a "vaccine injury." According to the petitioner, the clock should begin to run only when it was known that the vaccine caused the complained-of specific injury. Nevertheless, all of this is contrary to *Markovich*, which held that the limitations period begins to run at the first occurrence of a symptom even though an exact diagnosis may be impossible until some future date when more symptoms or medical data are forthcoming. 477 F.3d at 1358-59. Logical or not, unfair or not, this is what Congress intended. *Id.* at 1358 ("the terms of the Vaccine Act demonstrate that Congress intended the limitations period to commence to run *prior* to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action" (emphasis added)); *Brice*, 240 F.3d at 1368-69, 1372-73. Indeed, the Chief Special Master, applying *Markovich*, correctly observed that "[t]he Federal Circuit was very clear that diagnosis is not the test for the purposes of the statute of limitations." *Cloer I* at *8.

Another of petitioner's objections is based on based on 42 U.S.C. § 300aa-11(c)(1)(D)(i). This provision requires that a petition under the Vaccine Act contain an affidavit or other supporting material that a petitioner has "suffered the residual effects or complications of

such illness, disability, injury, or condition for more than six months after the administration of the vaccine." Characterizing this language as a tolling provision, petitioner argues that the Chief Special Master erred in dismissing her petition because the limitations period could not begin to run until her injury persisted for six months, which did not occur until 2003-04 (which would thus make her claim timely). Pet.'s Mem. 22-23. The assertion that this requirement has any relation to the Vaccine Act's 36-month statute of limitations has no support in case law, the text of the statute of limitations, or the text of this six-month requirement. Section 300aa-11(c) merely contains the requirements for a petitioner to commence an action before the vaccine special master, one of which is a declaration that petitioner suffered from effects or complications six months after the administration of the vaccine. 42 U.S.C. § 300aa-11(c)(1)(D)(i). Therefore, this language is a condition precedent to the filing of the petition, not a limitations period cutting off the availability of an action.

Although also labeled as an arbitrary and capricious, abuse of discretion argument, petitioner's final "in accordance with law" question raises constitutional arguments. Pet.'s Mem. 30-33. These arguments, arising out of the Fifth Amendment's Due Process Clause, U.S. CONST. amend. V, are twofold: (1) that the Chief Special Master's construction of the Vaccine Act's limitations period impermissibly, in violation of equal protection precepts, discriminates against those victims of vaccines who, like Dr. Cloer, suffer from injuries that cannot be diagnosed within the Act's 36-month limitations period; and (2) that this construction denies petitioner her due process rights. Similar arguments have been addressed

by various courts. And each of these courts have uniformly rejected those arguments.

For instance, in *Leuz*, the parents of a boy who died following a vaccination raised arguments similar to those made by Dr. Cloer in the case at bar, although a different limitations period provision of the Vaccine Act was involved. 63 Fed. Cl. at 604. At issue was 42 U.S.C. § 300aa-16(a)(3), which requires that claims alleging death due to a vaccination be filed within 24 months of the death. The *Leuz* petitioners contrasted this with the non-death injuries, for which § 16(a)(2) (the provision at controversy in our case) provides for a 36-month limitations period following the injury. *Id.* The petitioners did not dispute that they filed their petition 33 months after their son's death, but instead contended that the Act violated their rights to equal protection and due process because the limitations period for death injuries was shorter than the 36-month limitations period for all other injuries under the Vaccine Act. *Id.* at 605.

The court rejected their constitutional arguments. Opining that rational basis review applied because the petitioners' Vaccine Act equal protection discrimination claims[8] did not implicate any fundamental right, the court concluded that the differing limitations period passed constitutional muster so long as it was reasonably related to a permissible government goal. *See id.* (citing *Black v. Sec'y of Health & Human Servs.*, 93

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[8] "Although," as the court explained, "the Fifth Amendment contains no equal protection clause," it forbids discrimination that is "so unjustifiable as to be violative of due process.'" *Id.* at 608 (quoting *Schneider v. Rusk*, 377 U.S. 163, 168, 84 S. Ct. 1187, 12 L. Ed. 2d 218 (1964) (quoting *Bolling v. Sharpe*, 347 U.S. 497, 499, 74 S. Ct. 693, 98 L. Ed. 884 (1954))).

F.3d 781, 787 (1996)). The court noted that "Congress is not obligated to extend the coverage of the Vaccine Act cases to all person [sic] suffering a vaccine-related injury." *Id.* (citing *Black*, 93 F.3d at 788; *Califano v. Boles*, 443 U.S. 282, 296, 99 S. Ct. 2767, 61 L. Ed. 2d 541 (1979)). Contrary to petitioners' claim that it was irrational, the court found logical reasons, and thus a rational basis, for the distinction—while in a non-death case, symptoms continue to evolve, and may need more time to diagnose, the events surrounding a death are static, and preclude the injury from worsening, changing, abating, or evolving. *See id.* at 608-09.

Nor did the limitations period run afoul, according to the court, of either substantive or procedural due process. Thus, the court determined that the limitations period did not violate substantive due process because it neither shocked the conscience nor interfered with any right implicit in the concept of ordered liberty. *Id.* at 609-10 (citing *United States v. Salerno*, 481 U.S. 739, 746, 107 S. Ct. 2095, 95 L. Ed. 2d 697 (1987) (quoting *Rochin v. California*, 342 U.S. 165, 172, 72 S. Ct. 205, 96 L. Ed. 183 (1952))). Rather, the court noted that the 24-month period is "rationally related to the Act's dual purposes of settling claims quickly and easily, without collateral litigation, and protecting manufacturers from uncertain tort liability." *Id.* at 610. In sum, the court concluded that "the petitioners have not persuasively argued that the statute of limitations has operated in any manner contrary to its legislative purpose." *Id.* Similarly, the court concluded that the limitations period did not violate procedural due process. *Id.* at 610-11. Because petitioners had no vested right in any claim for damages until there is a final judgment, they had only a "unilateral expectation" that does not rise to a level of

entitlement. *Id.* (citing *Board of Regents v. Roth*, 408 U.S. 564, 577, 92 S. Ct. 2701, 33 L. Ed. 2d 548 (1972); *Hammond v. United States*, 786 F.2d 8, 12 (1st Cir. 1986)). Moreover, the court, in applying the balancing test under *Mathews v. Eldridge*, 424 U.S. 319, 335, 96 S. Ct. 893, 47 L. Ed. 2d 18 (1976),[9] concluded that tolling the limitations period as petitioners requested would come at a great societal cost by harming public health and thus would be inconsistent with the Act's overall statutory scheme. *See id.* at 611-12.

An even more apropos case is *Blackmon*. In facing equal protection and due process constitutional challenges to § 16(a)(2)'s 36-month limitations period—the same limitations period in controversy here—the court faced an argument similar to that made by Dr. Cloer: the Vaccine Act's limitations period unconstitutionally discriminated against those with latent, slow-developing vaccine injuries that cannot be fully diagnosed until the 36-month period has run. *Blackmon*, 328 F. Supp. 2d at 655. While emphasizing that the limitations period did impose a hardship on some people, because the statute of limitations was only subject to rational basis review, the 36-month limitations period bore a clear and logical connection to a "repose" purpose of the Vaccine Act in protecting vaccine manufacturers from open-ended lawsuits in order to maintain the supply of vaccines. *Id.*

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[9] These factors include: "(1) the strength of the private interests that would be affected by the official action; (2) the 'risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards,' and (3) 'the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.'" *Leuz*, 63 Fed. Cl. at 611 (quoting *Mathews*, 424 U.S. at 335, 96 S. Ct. 893).

(citing *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994)).

The plaintiffs' other Fifth Amendment argument (again, much like Dr. Cloer's) asserted that the Act's statute of limitations, expiring before the plaintiffs knew or could have known of their children's vaccine injuries, violated the constitutional guarantee of due process. *See id.* at 655-56. In rejecting petitioners' assertions, the court observed the well-settled rule that "[t]he Due Process Clause does not entitle every litigant to a hearing on the merits in every case," and emphasized that statutes of limitations are themselves common and unremarkable means to avoid stale claims and provide an end-date to potential litigation. *See id.* at 656. The court noted that plaintiffs failed their burden to prove that the Vaccine Act's limitations period was "wholly arbitrary." *Id.* (citing *Montagino v. Canale*, 792 F.2d 554, 557 (5th Cir. 1986)). Indeed, to the court, "[t]he mere fact that certain victims fail to discover and file their claims before the limitations period expires, while regrettable, does not render the limitation unreasonable." *Id.* at 656-57 (quoting *Ciccarelli v. Carey Canadian Mines Ltd.*, 757 F.2d 548, 555 (3d Cir. 1985) ("Because statutory periods are in some sense arbitrary, the period to initiate suit occasionally expires before a claimant has sustained any injury . . . or before the claimant knows he has sustained an injury . . . ."). Instead, the limitations period was constitutional because "it is reasonably calculated to serve a permissible legislative goal." *Id.*

The equal protection and due process arguments proffered by petitioner in the case at bar must be rejected for the reason the virtually-same arguments were

rejected by the *Leuz* and *Blackmon* courts—there can be no question that applying the Vaccine Act's limitation period is rationally related to the dual legitimate legislative purposes undergirding the Vaccine Act: (1) the settling of claims quickly and easily,[10] and (2) the protecting of manufacturers from uncertain liability making "production of vaccines economically unattractive, potentially discouraging vaccine manufacturers from remaining in the market." *Brice*, 240 F.3d at 1368. And because petitioner also lacks a vested property interest in her claim, it is difficult to see a Fifth Amendment due process violation.

B. Was *Cloer I* an Abuse of Discretion or Arbitrary and Capricious?

Turning to this set of objections, petitioner contends that it was an abuse of discretion or arbitrary and capricious of the Chief Special Master not to account for the "insidious[ ]" development of MS and the difficulties in diagnosing it, especially as MS was not listed as an injury for any vaccine on the Table. Pet.'s Mem. 23-24. In other words, petitioner maintains that an exception should have been made to the restrictive view of the limitations period because petitioner did not and could not receive a definitive diagnosis for her particular demyelinating disease until 2003. *See, e.g.*, Pet.'s Mem. 21, 24. Yet this is another *Setnes* argument that petitioner tries to dress up in new garb. At its heart it is a matter of the

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[10] *See* H.R. REP. NO. 99-908, at 17, *reprinted in* 1986 U.S.C.C.A.N. at 6358 ("[M]uch of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the petitioner can expect judgment; without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner.").

interpretation of the limitations period provision, which is a pure legal issue, not one of whether the Chief Special Master's marshaling of the evidence was unreasonable or arbitrary.

Nevertheless, even using the arbitrary and capricious rubric, and contrary to petitioner's contention, the Chief Special Master did not abuse his discretion, nor act arbitrarily or capriciously, in refusing to carve out an atextual exception for petitioner's particular claimed injury. The record would not allow it. To be sure, as far back as 1998, plaintiff's own expert, Dr. Meyer, considered MS to be a possible cause of Dr. Cloer's symptoms. *Cloer I* at *1 ("May 15, 1998 record of UM-Columbia noted '[p]robable early inactive non- progressive CNS [central nervous system] demyelination/MS'"). In retrospect, Dr. Meyer similarly concluded that the first sign of MS was the Lhermitte Sign that Dr. Cloer experienced in 1997. *Id.* at *4. It is this Lhermitte sign, which was then indicative of MS and remains so today, that was the "first symptom" (or perhaps even a "manifestation of onset") of what is by definition a vaccine injury under the Act. *See Brice*, 240 F.3d at 1373 (observing that for the purpose of the Vaccine Act's limitations period the first symptom of a vaccine injury may predate the final diagnosis of a disease). That Dr. Cloer was finally able, in 2003, to definitively attach a particular name to the symptoms that she had on and off for six years does not and cannot mean that she did not suffer a vaccine injury until 2003. The statute of limitations does not provide "first clinically *definitive symptom* or manifestation of onset of a medical syndrome;" rather, it is sparked by the "first symptom or manifestation of onset of a vaccine injury." *See* 42 U.S.C. § 300aa-16(a)(2).

Furthermore, there is other evidence in the record that supports the Chief Special Master's conclusion that the first symptoms of MS occurred prior to 2003. In May 1999, Dr. Colapinto traced the beginning of petitioner's neurological symptoms, which "likely represent demyelinating disease," back to the numbness in Dr. Cloer's left arm and hand that accompanied her Lhermitte sign. *Id.* at *1. Similarly, Dr. Wood, in 2003, and Dr. Metcalf, in 2004, both trace petitioner's first symptoms back to her neurological problems of 1997. *See id.* at *2.

Similarly, petitioner's other "arbitrary and capricious" arguments are really "not in accordance with law" objections. Nor are they persuasive. For instance, the petitioner asserts that by rejecting the application of *Setnes* to the instant facts, *Cloer I* is not only not in accordance with law, but also is an abuse of discretion or arbitrary and capricious. Pet.'s Mem. 24-25. The Chief Special Master concluded, and this court agrees, that *Setnes* does not apply to the instant facts, *Cloer I* at *4-*5, and that even if it did, as stated above, *Setnes* is contrary to *Markovich*, which, unlike *Setnes*, is binding upon this court. Petitioner likewise contends that the Chief Special Master's decision to deny compensation is arbitrary and capricious because it violates the remedial purpose of the Vaccine Act, which is demonstrated by its generous provisions and because it is less adversarial than a product liability lawsuit. Pet.'s Mem. 25-28. But of course, it is the duty of the Chief Special Master here to enforce the Vaccine Act's specific limitations provision, the meaning of which is the best exemplar of congressional intent. *See Nixon v. United States*, 506 U.S. 224, 232, 113 S. Ct. 732, 122 L. Ed. 2d 1 (1993) (observ-

ing "the well-established rule that the plain language of the enacted text is the best indicator of intent").

Yet another "arbitrary and capricious" objection by petitioner is that the Chief Special Master ignored her proffered "unrebutted expert testimony" supporting her position. Pet.'s Mem. 29-30. This objection is also vague and not well-developed. Petitioner failed to detail which "unrebutted" testimony the Chief Special Master ignored. In fact, there is no evidence that Chief Special Master Golkiewicz ignored or failed to weigh testimony on *any medical issue* in the case. Yet there remains one other proffered argument that falls into the "vague and not well-developed" category. In asserting yet another *Setnes* argument, petitioner argues that because she did not find out until 2005 that the Hep-B vaccinations to which she traces her MS contained Thimerosal, the court must liberally construe the Vaccine Act's 36-month statute of limitations to begin to run on the diagnosis of the disease rather than trigger on its first symptom or the manifestation of its onset.[11] Pet.'s Mem. 33-34. Petitioner further claims that *Cloer I* fails to address recent concerns on Thimerosal and the potential bearing of this new information on the accrual of her claims under the Vaccine Program. Pet.'s Mem. 34. Besides the fact that there is no evidence that petitioner raised this issue before the Chief Special Master, neither the potential effects of Thimerosal nor its inclusion in the Hep-B vaccine have any bearing on whether petitioner sought com-

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[11] Thimerosal is a compound that had been added to vaccines as a preservative and is the subject of a number of claims alleging that it causes vaccine injuries, most notably but not exclusively autism spectrum disorder. *See generally* Thimerosal in Vaccines, http://www.fda.gov/CBER/vaccine/thimerosal.htm. An examination of the effects of Thimerosal is beyond the scope of this opinion.

pensation within three years of the first symptom or manifestation of the onset of her demyelinating disease.

To be sure, this court has an enormous amount of sympathy for petitioner's predicament—MS is not easy to diagnose, its etiology remains largely unknown, and its manifestation and symptoms are episodic, waxing and waning, disappearing and recurring. *See* note 3, *supra*. That petitioner may be without relief for her MS gives this court no small measure of discomfort. But, as the Federal Circuit noted in *Brice*, weighing the pros and cons of a particular statutory scheme is a problem for Congress to address. 240 F.3d at 1373. The 36-month limitations period of the Vaccine Act is neither unlawful nor unconstitutional. Nor was the Chief Special Master's decision arbitrary, capricious, or an abuse of discretion.

IV. CONCLUSION

For the foregoing reasons, the court **AFFIRMS** the Special Master's decision. The court, accordingly, dismisses the petition with prejudice.

IT IS SO ORDERED.

APPENDIX F

UNITED STATES COURT OF FEDERAL CLAIMS

No. 05-1002V

MELISSA CLOER, M.D., PETITIONER

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, RESPONDENT

May 15, 2008

DECISION[1]

GOLKIEWICZ, Chief Special Master.

On September 16, 2005, petitioner, Melissa Cloer, M.D. (Dr. Cloer), filed a Petition pursuant to the Nat-

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[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire" decision will be available to the public. *Id.*

ional Vaccine Injury Compensation Program[2] ("the Act" or "the Program") alleging that she "had sustained and/or significantly aggravated Multiple Sclerosis[3] (MS) as a result of receiving Hep-B immunizations in 1996 and 1997."[4] Petition (Pet.) at 1. On December 1, 2005, respondent filed a Motion to Dismiss alleging the Petition was filed outside the statutorily prescribed limitations period. Respondent's Motion to Dismiss (hereinafter R Motion to Dismiss) at 1. Multiple pleadings and affidavits were subsequently submitted by the parties addressing the issue of whether the above-captioned

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[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 *et seq.* (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act"). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

[3] Multiple Sclerosis (MS) is defined as: a disease in which there are foci of demyelination of various sizes throughout the white matter of the central nervous system, sometimes extending into the gray matter. Typically, the symptoms of lesions of the white matter are weakness, incoordination, paresthesias, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that the term *multiple* also refers to remissions and relapses that occur over a period of many years. Four types are recognized, based on the course of the disease: *relapsing remitting, secondary progressive, primary progressive,* and *progressive relapsing*. The etiology is unknown. Dorland's Illustrated Medical Dictionary 1669 (30th ed 2003).

[4] The undersigned notes that while petitioner alleged in her petition she "had sustained and/or significantly aggravated Multiple Sclerosis (MS) as a result of receiving Hep-B immunizations in 1996 and 1997," petitioner did not produce any evidence distinguishing between "sustained" and "aggravated" for purposes of determining whether the Petition was filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." § 16(a)(2).

case was timely filed. Ultimately, a telephonic Hearing was convened to elicit testimony from petitioner's treating physician, Dr. Michael Andrew Meyer. Petitioner and respondent subsequently filed post-Hearing briefs. The issue is ripe for resolution.

Issue

The sole issue presented at this stage in the proceedings is whether Dr. Cloer's Petition for compensation for her *multiple sclerosis* injury was filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." § 16(a)(2).[5] For the reasons set forth below the undersigned must dismiss this petition as untimely filed.

Facts

The facts presented in this matter are uncontested, although the significance of the facts is the centerpiece of the dispute. Dr. Cloer was born on January 22, 1968. Pet. at 1. Prior to Dr. Cloer's MS injury she had no significant medical issues and enjoyed good health. *Id.* at 2. Dr. Cloer received a series of three Hep-B vaccinations on September 3, 1996, November 11, 1996, and April 3, 1997. *Id.* The following excerpt from respon-

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[5] The undersigned requested the parties to address the applicability of the Act's distinct time period for filing a claim based upon a revision to the Vaccine Injury Table. *See* § 16(b). Respondent raised the issue in Respondent's Reply to Petitioner's Opposition to the Motion to Dismiss at 6-7. Petitioner argued that § 16(b) was inapplicable. Petitioner's Response to Respondent's Argument Regarding the Applicability of § 16(b). Thereafter, respondent's counsel indicated to the undersigned in a joint status conference with petitioner's counsel on May 15, 2006 that respondent agreed with petitioner's position. Given the resolution of this case, it is unnecessary to discuss the § 16(b) issue.

dent's post-Hearing brief fairly and accurately summarizes petitioner's pertinent medical records following her three Hep-B vaccinations.

1. April 28, 1998 records of UM–Columbia reveal that one year earlier petitioner complained of an "electric-like shock sensation going down [the] center of [her] back into both feet," and, in September and October 1997, petitioner lost sensation in her left arm and left hand. Petitioner's Exhibit ("Pet. Exh.") 12 at 12;

2. May 12, 1998 magnetic resonance imaging (MRI) scan; possible diagnoses included "multiple sclerosis, lyme[ ] disease, ADEM [acute disseminating encephalomyelitis], or other demyelinating processes." Pet. Exh. 12 at 16;

3. May 15, 1998 record of UM–Columbia noted "[p]robable early inactive non-progressive CNS [central nervous system] demyelination/MS. . . ." Pet. Exh. 12 at 17;

4. June 23, 1998 electromyography (EMG) to evaluate "numbness and tingling in the L ulnar nerve distribution." Pet. Exh. 12 at 22;

5. May 6, 1999 neurological examination by Ted Colapinto, M.D. Pet. Ex. 12 at 36. Dr. Colapinto noted petitioner's history "beg[an] approximately two years ago when she had the onset of neurological symptoms in her left hand. She complain[ed] that her left hand felt numb . . . this lasted approximately two months, but gradually resolved mostly." *Id.* Dr. Colapinto recorded petitioner's complaints of numbness in her face, arms, and legs, and noted that she had difficulty walking. *Id.* He felt that peti-

tioner's neurological symptoms "likely represent demyelinating disease." *Id.*;

6. June 3, 1999 follow-up visit to Dr. Colapinto noted "a lot of improvement in the symptoms in the lower extremities, but still notice[d] some feelings of proximal weakness in the right leg, as well as some numbness of the anterior aspect of the right thigh." Pet. Exh. 12 at 41. Dr. Colapinto expressed continuing concern that petitioner had a demyelinating disease. *Id.*;

7. November 26, 2003 record of Dr. Wood detailing petitioner's medical history:

> [Melissa] actually believes that she has had problems dating from 1997 when she was in Missouri. She had episodes of variable weakness and numbness of her legs, at one time numbness of her right face. She had an MRI of the brain in 1997 which reportedly was suspicious for demyelinating areas and also had spinal cord MRIs reportedly unremarkable . . . She had actually been recommended for treatment for MS, but did not take any. Pet. Exh. 13 at 17.[6]

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[6] The undersigned notes that Dr. Johnson, who evaluated Dr. Cloer in August of 2002 for symptoms consistent with retrobulbar neuritis, submitted an affidavit in this case stating "[t]o the extent Dr. Wood's note indicates that Dr. Cloer was recommended for treatment for MS, but did not take any, that would not apply to my care and treatment of Dr. Cloer." Pet. Exh. 21 at 2. Dr. Johnson also disputes a notation in Dr. Wood's November 26, 2003 record indicating Dr. Cloer was urged to get treatment for retrobulbar neuritis in the fall of 2002. Dr. Johnson states Dr. Cloer had "symptoms in the left eye when I consulted with her. I did not urge any treatment." *Id.* The undersigned finds it

Respondent's Reply to Petitioner's Post-Hearing Brief (hereinafter R. Post-Hearing Reply) at 3-4.

Dr. Cloer was given a "provisional" diagnosis of MS on November 26, 2003 by her treating neurologist Dr. Wood subsequent to his obtaining Dr. Cloer's medical history and results of an MRI examination. Pet. Exh. 13 at 16–19.

Dr. Cloer applied for and was awarded Social Security Disability in 2004. Pet. Exh. 14 at 1–2. As part of that process Dr. Cloer was evaluated by Dr. James P. Metcalf on June 17, 2004. *Id.* at 3. Dr. Metcalf noted Dr. Cloer reported she "first begin [sic] to have some symptoms consistent with MS in 1997," however, her "symptoms waxed and waned until the fall of 2003 when she begin [sic] to have manifestations of the full blown disease." *Id.*

Dr. Cloer reported to the Vaccine Adverse Event Reporting System (VAERS) on October 11, 2004, that she experienced numbness and tingling after her first two Hep–B vaccinations. Pet. Exh. 19 at 2. Dr. Cloer stated these symptoms were followed by "Lhermitte's"[7] approximately one month after her third vaccination. *Id.*

AFFIDAVITS OF MELISSA L. CLOER, MD

Dr. Cloer, petitioner, submitted a sworn affidavit as part of the Petition in this case. The critical portion relevant to the issue at hand states as follows:

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is not necessary to determine whether or not Dr. Johnson recommended Dr. Cloer receive MS treatment in 2002 to resolve the issue presented in the instant case.

[7] Lhermitte's phenomenon is discussed at n.8, infra at p. 7.

12. In late 2003, I was diagnosed with multiple sclerosis. While I had experienced some isolated symptoms prior to that time, it wasn't until November 2003 that probable multiple sclerosis was diagnosed.

13. For instance, in 1997 I had an electric shock sensation in my spine and numbness in my left forearms and hand. My family physician, Dr. Susan Pereira, prescribed Motrin and the symptoms resolved over a short period of time. An MRI done on May 12, 1998 included differential diagnoses of MS, Lymes Disease, ADEM or other demyelinating processes. Dr. Meyer, the neurologist, described my problem as a "probable early inactive non-progressive" condition.

Pet. Exh. 2 at 3. As the legal issue of whether her Petition was filed timely developed, petitioner thereafter filed a second affidavit. Pet. Exh. 26. The affidavit provides in relevant part as follows:

4. I have been asked to address when any of the signs, the first occurrence of the first symptom or manifestation of onset of my Multiple Sclerosis (MS) lasted six months or more.

5. It was not until late 2003 or early 2004 that any signs, the first symptoms or manifestation of onset of my Multiple Sclerosis persisted for six months or more.

Id.

AFFIDAVITS FROM DR. MICHAEL MEYER

Dr. Meyer is a neurologist who treated petitioner in 1998, about one year following her immunizations. Dr. Meyer's first affidavit was filed on February 16, 2007. Pet. Exh. 20. In relevant part, Dr. Meyer stated that at

the time he examined Dr. Cloer, "she had the manifestations of onset of what can be termed 'singular sclerosis' . . . [and] she had what appeared to be early inactive non-progressive CNS demyelinating disease." *Id.* He also stated that:

> 10. At the time I evaluated Dr. Cloer in 1998, she had not yet been formally diagnosed with the clinical syndrome complex of multiple sclerosis (MS).
>
> 11. There had been no manifestation for the onset of clinically definite multiple sclerosis during the time period I evaluated Dr. Cloer.

Id. Following a number of status conferences between the undersigned and counsel discussing the statute of limitations issue, petitioner filed a second affidavit from Dr. Meyer. Pet. Exh. 23. In that affidavit, Dr. Meyer expanded on and explained statements he made in his earlier affidavit. *Id.* Relevant to the issue at hand, Dr. Meyer maintained that when he evaluated Dr. Cloer in 1998, she did not meet "formal diagnostic criteria for clinically definite MS." *Id.* He explained that at that time in 1998, Dr. Cloer's "singular demyelinating change could have remained a clinically isolated event with no sequela." *Id.*

Following the Court of Appeals for the Federal Circuit's decision in *Markovich v. Secretary of HHS*, 477 F.3d 1353 (Fed. Cir. 2007), which addressed the appropriate legal interpretation of the Act's statute of limitations, Dr. Meyer issued a third affidavit. Pet. Exh. 25. In this affidavit, Dr. Meyer repeats the medical points made in his two prior affidavits. In addition, having been provided by counsel a copy of the *Markovich* opinion, Dr. Meyer attempts to interpret and apply *Marko-*

vich to the medical facts of Dr. Cloer's case. Obviously, it is not Dr. Meyer's role as a medical expert to interpret the law, and his efforts were not helpful.

After reviewing Dr. Meyer's three affidavits and discussing them with counsel, it was clear that Dr. Meyer's testimony was necessary to understand several points, including what he meant by "she had the manifestations of onset of what can be termed 'singular sclerosis'" in 1998, Pet. Exh. 20, and "[t]here had been no manifestation for the onset of clinically definite multiple sclerosis during the time period I evaluated Dr. Cloer." *Id.* A Hearing was conducted to take Dr. Meyer's testimony.

DR. MEYER'S TESTIMONY

Michael Andrew Meyer, M.D., testified without objection as an expert in the field of neurology with a speciality in MS. Hearing Transcript (hereinafter "Tr. at __") at 9. Dr. Meyer testified consistently with his affidavits. He was extremely knowledgeable about the medical issues involved and, having reviewed the medical records, was well-prepared to discuss the case. The undersigned found Dr. Meyer to be a very credible witness. However, at times Dr. Meyer's testimony appeared contradictory and confusing. But this was not the fault of Dr. Meyer, and was not interpreted in any way to detract from his credibility. The confusing testimony was the direct result of questions from petitioner's counsel designed to finesse the facts of this case into the legal standard crafted by the Federal Circuit in *Markovich*. Dr. Meyer struggled at times with his answers to these questions, answers the undersigned found unhelpful. Dr. Meyer's testimony regarding the medical issues was clear and convincing. These issues will be discussed later.

During his testimony, Dr. Meyer summarized petitioner's medical history beginning when he first evaluated petitioner on April 28, 1998 at the University of Missouri Medical Clinic. Tr. at 11; Pet. Exh. 12 at 12. Dr. Meyer testified that his notes from his initial evaluation with Dr. Cloer indicate she complained of experiencing one year ago, in 1997, "electric like sensations going down the center of her back to both feet with forward head flexion"[8] for several months. Tr. at 12; Pet. Exh. 12 at 12. Dr. Cloer also reported to Dr. Meyer that she experienced "decreased sensation at the left posterior shoulder area and back" in 1997. *Id.* Dr. Meyer explained based upon the history taken, as well as his physical examination of Dr. Cloer, he ordered an MRI scan "to rule out MS." *Id.* at 12-13. Dr. Meyer testified that in 1998 "he did not think she [Dr. Cloer] had definite MS at that time." Tr. at 15, 34. However, Dr. Meyer testified that in retrospect petitioner's experience of Lhermitte's sign in 1997 was the first symptom of Dr. Cloer's MS. *Id.* at 49-50, 52, 54-55.

LEGAL STANDARD

Pursuant to the Vaccine Act petitioners may be compensated for injuries caused by certain vaccines. 42 U.S.C. §§ 300aa-10 to -34. However, the Vaccine Act provides statutory deadlines for filing program petitions

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[8] Dr. Meyer testified at the Hearing that this "sensation" experienced by Dr. Cloer is Lhermitte's phenomenon. Tr. at 34–35. Lhermitte's sign is defined as "the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in multiple sclerosis but also in compression and other disorders of the cervical cord." Dorland's Illustrated Medical Dictionary 1700 (30th ed 2003).

at § 300aa-16. In relevant part, the Vaccine Act provides:

> a vaccine set forth in the Vaccine Injury Table which is administered after [October 1, 1988], if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the **expiration of 36 months** after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury. . . .

§ 300aa-16(a)(2) (emphasis added). The Vaccine Act is a waiver of the United States' sovereign immunity and accordingly "must be strictly and narrowly construed." *Markovich v. Secretary of HHS*, 477 F.3d 1353, 1356 (Fed. Cir. 2007). The Federal Circuit has instructed "courts should be careful not to interpret a waiver in a manner that would extend the waiver in a manner beyond that which Congress intend." *Markovich*, 477 F.3d at 1360, citing *Brice v. Secretary of HHS*, 240 F.3d 1367, 1370 (Fed. Cir. 2001). The Circuit's decision in *Markovich* directly addressed the question of "what standard should be applied in determining the date of 'the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury,'" *Markovich*, 477 F.3d at 1356, by holding "'the first symptom or manifestation of onset,' for purposes of § 300aa16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." *Id.* at 1360.[9] Accordingly, petitioners have 36 months from

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[9] Although not directly stated, the *Markovich* decision appears to have found that *Setnes v. Secretary of HHS*, 57 Fed. Cl. 175 (2003) was incorrectly decided. In *Setnes*, the Court of Federal Claims determined

the first recognizable sign of their alleged vaccine injury to file their claim.

The Circuit explained in *Markovich* that "the terms of the Vaccine Act demonstrate that Congress intended the limitation period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." *Id.* at 1358. The Circuit elaborated that by choosing to "start the running of the statute of limitations period on the date the first symptom or manifestation of the onset occurs, Congress chose to start the running of the statute before many petitioners would be able to recognize with reasonable certainty, the nature of the injury." *Id.* The Court noted that the Act has "consistently been interpreted" to include "subtle" symptoms or manifestations of onset as triggers of the Act's statute of limitations. *Id.* The Court stressed that the words "symptom" and "manifestation of onset" are in the disjunctive as used in the Act and that the words have different

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that "[w]here there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on the 'occurrence of the first symptom.'" *Setnes*, 57 Fed. Cl. at 179. The *Setnes* court stated that because the symptoms of autism develop "insidiously over time" and the child's behavior cannot readily be connected to an injury or disorder, the court's inquiry into the onset of the autistic condition is not limited to a determination of when the first symptom or manifestation of the condition occurred, but rather is informed by the child's subsequent medical or psychological evaluations of when the "manifestation of onset" occurred. *Id.* at 181. The Federal Circuit found a "significant problem with the rationale of *Setnes*" in that *Setnes* "effectively" required evidence of a "symptom *and* manifestation" whereas the Act requires either a symptom or manifestation of onset, whichever occurs first, to trigger the statute of limitations. *Markovich*, 477 F.3d at 1358.

meanings. *Id.* at 1357. Thus, **symptom** "may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury," whereas a **manifestation of onset** "is more self-evident of an injury and may include significant symptoms that clearly evidence an injury." *Id.* Accordingly, the Court found that the Act's statutory standard of first symptom or manifestation of onset could include subtle symptoms that a petitioner would recognize "only with the benefit of hindsight, after a doctor makes a definitive diagnosis of the injury" and would be "recognizable to the medical profession at large but not necessarily to the parent." *Id.* at 1358, 1360 (citing *Goetz v. Secretary of HHS*, 45 Fed. Cl. 340, 342 (1999)). Thus, the Circuit in interpreting the Act's statute of limitations, rejected applying a "subjective standard that focuses on the parent's view" of the timing of onset in favor of an "objective standard that focuses on the recognized standards of the medical profession at large." *Id.* at 1360.

Discussion

The undersigned notes that the complexity of the issues presented in this case evolved with the development of the case law. The initial arguments and discussions took place within the context of the *Setnes* ruling, which unquestionably presented much reasonable room for disagreement and debate. However, with the issuance of the Circuit's decision in *Markovich*, the standard for resolving issues under the Act's statute of limitations has crystalized and the room for debate narrowed greatly. In light of *Markovich*, the issues presented in this case are now relatively straightforward.

After considering the entire record and the parties' respective arguments, this case must be dismissed as untimely. It is clear from the medical records, petitioner's affidavits, as well as Dr. Meyer's affidavits and testimony that the first symptom of the onset of Dr. Cloer's MS was in 1997. Since the Petition was filed eight years later, the Petition was untimely. *See* § 16(a)(2).

Dr. Meyer conceded several times at the August 30, 2003 hearing that in **retrospect** the first symptom of Dr. Cloer's MS was the Lhermitte's sign which Dr. Cloer experienced in 1997.

> THE COURT: [Y]ou said back in 1998 [petitioner] had a singular sclerosis. Looking back at this case now from today's vantage point is that singular sclerosis part of what was ultimately diagnosed as multiple sclerosis?
>
> DR. MEYER: Retrospectively I think that there was a relation, and I think that it's probably linked in some way. You know, we're talking about a disease that's not uncommon, and prospectively the symptoms could have represented many different things. The [Lhermitte's] phenomenon that she does talk about or had talked about does raise some concern about MS specific type symptoms.
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> Tr. at 49.
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> THE COURT: [F]rom today with the totality of this record was that singular sclerosis part what was ultimately diagnosed as multiple sclerosis?
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> DR. MEYER: I can't say definitely. I say that there's a likelihood that there's a relationship, that

there's probably a link. A more yes than no, but I can't say definitely.

THE COURT: Okay. So I interpret that to mean on a probability scale that you would say it was more probably than not related?

DR. MEYER: Yes. More probably yes than no.

Tr. at 49–50.

THE COURT: [L]ooking back at this retrospectively with this record you have in front of you, on a probability scale what's the first evidence of her multiple sclerosis?

WITNESS: I think that the first MS related symptom was the [Lhermitte's] phenomenon that she had in 1997 where she would have the electric shock like sensation going down her back when she would bring her head forward.

Tr. at 52.

In response to questioning, Dr. Meyer agreed that petitioner had a demyelinating disease in 1998. Tr. at 37. However, she did not have the requisite number of lesions to have clinically definite multiple sclerosis. *Id.* Eventually, petitioner's symptoms progressed to where it became multiple sclerosis. Tr. at 41. Dr. Meyer stated that although it is difficult and individual cases vary, a retrospective linking of past symptoms to a current diagnosis of multiple sclerosis can "find the connection often." Tr. at 39.

Dr. Meyer's retrospective testimony is consistent with the medical records in noting a demyelinating disease in Dr. Cloer in 1998. The contemporaneous medical

records are replete with references to demyelinating symptoms and to possible MS. *See* Pet. Exh. 12 at 17 (Dr. Meyer's 5/15/98 progress notes states "[p]robable early inactive non-progressive cns [central nervous system] demyelination/ms . . . "); *Id.* at 16 (5/12/98 MRI notes a clinical history of "DYMILANATING [sic] MS" (emphasis in original) and states under "IMPRESSION" "Multiple Sclerosis, Lymes Disease, ADEM, or other Demyelinating Processes"); *Id.* at 37 (Noting a two-year history of onset of neurological symptoms, Dr. Colapinto's posits in a May 6, 1999 letter that "[Dr. Cloer] is having waxing and waning neurological symptoms in multiple areas of her body. I fear that this may likely represent demyelinating disease."). Also, later records date the onset of Dr. Cloer's MS to the events of 1997. *See* Pet. Exh. 13 at 17 (Dr. Wood's 11/26/03 history noting that Dr. Cloer "had an MRI of the brain in 1997 which reportedly was suspicious for demyelinating areas . . . "); Pet. Exh. 14 at 3 (Dr. Metcalf's 6/17/04 examination of Dr. Cloer wherein he notes that Dr. Cloer "states she first began to have some symptoms consistent with MS in 1997.") (emphasis added); Pet Exh. 13 at 35 (Dr. Wood, providing medical information for a student financial aid application for Dr. Cloer in February of 2005, states "MRI proven Multiple Sclerosis of brain and spinal cord, 8 yrs duration," i.e., MS began in 1997).

In addition, petitioner's first affidavit acknowledged that in 1997, she experienced an "electric shock sensation" in her spine. Pet. Exh. 2 at 2. Petitioner also filed a VAERS report in 2004 stating that she suffered Lhermitte's approximately a month following her immunization. Pet. Exh. 19 at 2. Dr. Meyer testified that the shock-like sensation experienced by petitioner was

Lhermitte's phenomenon, tr. at 34-35, and that the "first MS related symptom was the [Lhermitte's] phenomenon that she had in 1997." *Id.* at 52.

Dr. Cloer's onset of MS also can be traced through the testimony of Dr. Meyer. Dr. Meyer first evaluated Dr. Cloer in 1998 and stated that Dr. Cloer had "demyelinating disease" at that time, but that "she did not yet have the requisite lesions in multiple areas of her central nervous system to qualify as clinically definite multiple sclerosis." Tr. at 37. Dr. Meyer explained that there is often a significant delay between the initial symptoms of MS and a definitive diagnosis of MS. Based upon the study of patient histories it is known that "patients who wind up with a definitive diagnosis of MS when they are looked [at] retrospectively there can be a great delay . . . a gap of many years." Tr. at 38. Dr. Meyer stated that the initial symptoms may progress, may wax and wan, or may never return. Tr. at 40, 43. It is a "fickle" disease. Tr. at 43. However, regarding Dr. Cloer, he stated:

> From what I know about what happened, what transpired over the years, that things did change, and in 2002 and 2003 she had progressed, changed.

Tr. at 40-41. In Dr. Cloer's case, Dr. Meyer testified her condition "became multiple sclerosis." Tr. at 41. Thus, Dr. Meyer agreed, it can be apparent retrospectively that symptoms which are part of the "same demyelinating process" may "culminate in a diagnosis of *multiple sclerosis* many years later." Tr. at 39. Dr. Meyer elaborated "retrospectively you can look back in this pool of patients and find the connection often," tr. at 39, and in Dr. Cloer's case the "first sign to a clinician retrospectively was the [Lhermitte's] phenomenon back

in 1997." Tr. at 55 (emphasis added); *see id.* at 49, 50, and 52.

The Act provides a window of three years from "the first symptom or manifestation of onset" to file a vaccine-related claim. § 16(a)(2). The Federal Circuit provided recently in *Markovich* the precedential interpretation of that section of the Act. Dr. Meyer testified that the first symptom of Dr. Cloer's MS occurred in 1997. The contemporaneous medical records support Dr. Meyer's testimony. Petitioner's contemporaneous histories given to treating doctors support the finding of the first symptom of her MS occurring in 1997. Lastly, petitioner's affidavit and statements on her VAERS reports state that the first symptom occurred in 1997. Accordingly, the undesigned finds that the overwhelming evidence supports a finding that the first symptom of Dr. Cloer's MS occurred in 1997. Thus, petitioner had three years, or until the year 2000, to file her vaccine injury claim. § 16(a)(2). Petitioner filed her claim on September 16, 2005. Clearly, petitioner filed her Petition beyond the Act's three-year statute of limitations. Accordingly, respondent's Motion to Dismiss is hereby granted.

Petitioner argues that the Vaccine Act's statute of limitations should not begin to run in the instant case until November of 2003 or thereafter based primarily upon the following: petitioner was not diagnosed with MS until 2003, neither petitioner nor her medical care providers were aware of a potential link between *vaccinations* and MS until after 2003, and MS poses diagnostic challenges. Thus, petitioner argues:

> The medical community at large would not have authoritatively associated her condition, injury or prob-

> lems to MS until 2003. It wasn't until after the November 2003 diagnosis of MS, based on accepted criteria, that Dr. Cloer became aware of the potential link to her earlier *immunizations*. There is no indication that other members of the "medical community at large" would have so linked her problems to the *vaccinations* until 2003 or thereafter.
>
> Petitioner's Post-Hearing Brief at 9.

Even assuming each of these arguments to be factually correct, these arguments fail, because petitioner misunderstands or chooses to ignore the standard enunciated by the Federal Circuit in *Markovich* and the plain language of the statute.

Throughout petitioner's briefs and even in questions posed to Dr. Meyer, petitioner raises the argument that there was no diagnosis of multiple sclerosis until November 2003. *See* Petitioner's Amended Brief in Opposition to Respondent's Motion to Dismiss (hereinafter P. Amended Brief in Opposition) filed February 17, 2006 at 3; *see also* Tr. at 26-27. Petitioner argues the statute of limitations should begin to run in 2003 at the earliest, relying upon Dr. Meyer's testimony that prior to petitioner's 2003 MRI, the medical community at-large would not have diagnosed Dr. Cloer with MS. Tr. at 27, 47, 55. Closely related to the argument of when the diagnosis was made is petitioner's contention that the "manifestation of onset" of Dr. Cloer's MS was in 2003. Petitioner's Post-Hearing Brief at 6; Tr. at 27-28. As discussed, *see supra* at pp. 7-8, the commencement of the Vaccine Act begins upon the *first symptom or manifestation* of the alleged vaccine related injury. The Federal Circuit interpreted that statutory language in the disjunctive, and recognized the "dissimilar meaning of

the words "symptom" and "manifestation of onset." *Markovich*, 477 F.3d at 1357. Dr. Meyer testified, and the medical records support, that the first symptom of petitioner's MS occurred in 1997. Having found the first symptom of Dr. Cloer's MS occurred in 1997, for purposes of the disjunctive standard of § 16(a)(2), it is thus irrelevant when the manifestation of onset occurred. Likewise, also irrelevant are petitioner's continued arguments regarding when the diagnosis of MS occurred. The Federal Circuit was very clear that diagnosis is not the test for purposes of the statute of limitations. *See id.* ("For example, in this case, the eye-blinking episode was a symptom of a seizure disorder without any diagnosis. . . . "); *see also id.* at 1358 ("[A] petitioner typically will recognize that a particular symptom constitutes the first symptom or manifestation of the onset of a certain injury only with the benefit of hindsight, after a doctor makes a definitive diagnosis of the injury.") (emphasis added).

A second argument that permeates petitioner's briefs and questions is that petitioner was not diagnosed with a vaccine injury before 2004. Petitioner's Post-Hearing Brief at 6; Tr. at 14, 20, 23, 26, and 28. Petitioner misreads *Markovich*. The Court's holding was that for purposes of § 300aa16(a)(2), "the first symptom or manifestation of onset" is the "first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." *Markovich* 477 F.3d at 1360. There is no requirement that the vaccine injury be diagnosed. In this case, the first "sign" of petitioner's MS, the alleged vaccine injury in this case, recognized by Dr. Meyer, a representative of the medical profession, tr. at 8, was the Lhermitte's phenomenon that occurred in 1997. Tr. at 52. Dr. Meyer's position is corroborated by both the

medical records and petitioner's affidavit. Accordingly, the first symptom for triggering the statute of limitations was the Lhermitte's phenomenon Dr. Cloer experienced in 1997.

Petitioner further argues the statute of limitations period should begin to run in 2003, because prior to this time petitioner did not suffer "the residual effects or complications of such illness, disability, injury or condition for more than six months," as required by § 11(c)(1)(D)(I) and thus could not have filed a valid petition. The undersigned agrees with respondent,

> whether or not a petitioner has shown that an injury has persisted for more than six months has no bearing on whether the petition was filed within 36 months of the first symptom or manifestation of onset of that injury. Section 11(c)(1)(D)(I) does not extend the filing date of a petition until a time when a petitioner's alleged vaccine-related injury persists for at least six months.
>
> R. Post-Hearing Reply at 5.[10]

---

[10] The undersigned notes petitioner raised a number of constitutional arguments in her filings in opposition to Respondent' Motion to Dismiss. Specifically, petitioner argues that the Vaccine Act's Statute of Limitations violates the Due Process or the Equal Protection Clause of the U.S. Constitution's Fifth Amendment. P. Amended Brief in Opposition at 17-23. Respondent strongly opposed petitioner's constitutional arguments. Respondent's Reply to Petitioner's Opposition to Respondent's Motion to Dismiss at 9-14. Petitioner's arguments were not well-developed. In any event, the undersigned finds it unnecessary to engage in a lengthy analysis since the criteria for eligibility has been analyzed and found to pass constitutional scrutiny. *Leuz. v. Secretary of HHS*, 63 Fed. Cl. 602 (2005).

Petitioner argues lastly that the statute of limitations should be tolled in the instant case as "there was no reason to suspect that Dr. Cloer's symptoms were in fact symptoms of MS" and as distinguishable from the *Brice* case as "there was neither a subjective nor an objective basis for drawing such a connection until some three years before the filing of Dr. Cloer's petition." P. Amended Brief in Opposition at 15. The undersigned disagrees. Upon taking petitioner's medical history and reviewing her MRI in 1998, Dr. Meyer did suspect MS as a potential diagnosis of petitioner's injury. In fact petitioner's medical records are replete with indications that her injury was potentially connected to MS in 1997 and 1998. *See supra* at pp. 2-4, and 10. Further, the Federal Circuit has found that "the statute of limitations [in the Vaccine Act] begins to run upon the first symptom or manifestation of onset of injury, even if the petitioner reasonably would not have known at that time that the vaccine caused an injury." *Brice v. Secretary of HHS*, 240 F.3d 1367, 1373 (Fed. Cir. 2001). In *Markovich*, the Circuit reaffirmed its' holding in *Brice* that "equitable tolling is not available for claims arising under § 300-16(a)(2)." *Markovich*, 477 F.3d at 1358.

For the reasons stated above and based upon the undersigned's review of the record as a whole, the undersigned finds that a preponderance of the evidence does not support that the Petition was filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury" as required by the Vaccine Act. Petitioner's claim is dismissed. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

APPENDIX G

1. 42 U.S.C. 300aa-11provides in pertinent part:

Petitions for compensation

(a) General rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) of this section with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa-12(d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death and—

* * * * *

2. 42 U.S.C. 300aa-12 provides in pertinent part:

Court jurisdiction

(a) General rule

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa-11 of this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under section 300aa-11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa-11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) of this section shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 300aa-13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa-11(c)(1)(C)(ii) of this title.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special masters which shall consist of not more than 8 special masters.
* * *

* * * * *

(6) The chief special master shall be responsible for the following:

* * * * *

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims on the number of petitions filed under section 300aa-11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

* * * * *

3. 42 U.S.C. 300aa-13 provides in pertinent part:

Determination of eligibility and compensation

* * * * *

(c) "Record" defined

For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa-11 of this title

4. 42 U.S.C. 300aa-15 provides in pertinent part:

Compensation

* * * * *

(e) Attorneys' fees

(1) In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover—

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reason-

able basis for the claim for which the petition was brought.

* * * * *

(f) Payment of compensation

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 300aa-21(a) of this title to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) of this section shall be paid from the date of the judgment of the United States Court of Federal Claims under section 300aa-12 of this title awarding the compensation. Such compensation may not be paid after an election under section 300aa-21(a) of this title to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

* * * * *

5. 42 U.S.C. 300aa-16 provides in pertinent part:

Limitations of actions

(a) General rule

In the case of—

* * * * *

(2) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed

for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

* * * * *

6. 42 U.S.C. 300aa-21 provides in pertinent part:

Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under section 300aa-12(f) of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa-11 of this title shall file with the clerk of the United States Court of Federal Claims—

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

* * * * *

OPPOSITION BRIEF

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No. 12-236

Supreme Court, U.S.
FILED
OCT 26 2012
OFFICE OF THE CLERK

In the Supreme Court of the United States

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

MELISSA CLOER,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED FOR REVIEW

Whether the Vaccine Act, which provides for the payment of attorneys' fees and costs incurred in connection with an unsuccessful claim for compensation brought pursuant to the Act, should be construed to permit the payment of such fees and costs in all circumstances except when a claim is unsuccessful because the statute of limitations has run.

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INTRODUCTION

The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§300aa-1 to 300aa-34 ("Vaccine Act" or "Act") provides the primary remedy for individuals who are injured by vaccines covered under the Act. All tort remedies based upon claims of defective design are barred. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011). The Act was designed to compensate victims of vaccine-related injuries "quickly, easily, and with certainty and generosity." H.R.Rep. No. 99–908, at 3 (1986), reprinted 1986 U.S.C.C.A.N. 6344, 6363. Attorneys who represent individuals suffering a suspected vaccine injury are prohibited from collecting fees apart from the fees paid to them from the Trust Fund established under the Act. 42 U.S.C. 300aa-15 (e) (3)[1].

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[1]In her Petition For Writ of Certiorari (the "Petition"), the Secretary of Health and Human Services (the "Secretary") refers to the Act's fee provision as a "fee-shifting" provision, but this is not accurate. A true "fee-shifting" provision requires one party to pay the fees that traditionally would be borne by an opposing party. Here, by contrast, the United States does not pay the fees incurred by claimants under the Act. Those fees are paid out of the Vaccine Injury Compensation Trust Fund, administered by the United States, but funded by a consumer-paid surcharge on vaccines. *See* 26 U.S.C. § 9510 (establishing the Trust Fund) and 26 U.S.C. § 4131 (imposing tax on the sale of vaccines). Currently, the Trust Fund has a balance of more than 2.4 billion (with a "b") dollars. *See* ftp://ftp.publicdebt.treas.gov/dfi/tfmb/dfivi0912.pdf. Moreover, because the Act provides that attorneys can only be paid fees from the Trust Fund, prohibiting private fee arrangements and payments, the fee provision is more accurately characterized not as a "fee shifting" provision, but as an attorney compensation provision or, more simply, a "fees and costs provision," which is how we refer to it.

The Vaccine Act provision for the payment of attorneys' fees and costs is broader than the typical "prevailing party" provision found in other federal statutes: the Vaccine Act not only mandates the recovery of fees by prevailing parties, it also permits the payment of fees and costs when a claim for compensation is denied, provided that the claim was brought in good faith and with a reasonable basis in fact. The Act's fee provision makes perfect sense: Congress provided that the Trust Fund would fully subsidize Vaccine Act litigation and accordingly, Congress provided the necessary incentive for attorneys to represent petitioners even when the validity of their claims is less than certain. Thus, the Act provides a mechanism for reimbursement of all costs, including attorneys' fees, in the event that claims, brought in good faith, prove unsuccessful for whatever reason.

Consistent with that purpose, Congress provided for an award of fees and costs in connection with "any proceedings" relating to a petition filed under section 300aa-11 of the Act, and the only statutory condition created by Congress on the payment of such fees incurred is that the claims, even if unsuccessful, were brought in good faith and with a reasonable basis. Congress drew no other distinctions about the types of unsuccessful claims filed pursuant to section 300aa-11 that could result in the payment of fees and costs including claims that are denied due to the running of the Act's statute of limitations.

And yet, the Secretary's Petition is devoted entirely to drawing exactly such a distinction, despite the fact that Congress itself did not do so. As we explain below, the Secretary's attempt to create a statutory

exception for the award of fees (that Congress itself did not create) should be rejected because it cannot be reconciled with the plain language of the Act. It similarly cannot be reconciled with the purpose of the fees and costs provision itself.

Nor should the Act's fee provision be rewritten in the manner urged by the Secretary (and the dissenting Judges in this case) based upon the parade of horrors that purportedly will result from the Federal Circuit's decision in this case. The primary vice that may result from the majority's decision is, the Secretary speculates, the necessity of conducting "shadow trials" when making fee decisions that will overwhelm the court system. These "shadow trials" would arise in cases that are denied on statute of limitations grounds, and where no judgment about the merits of a claim have been made. The Secretary asserts, then, that the merits nevertheless might have to be adjudicated in the context of a claim for fees and costs, because such an award can be made only on claims brought in good faith and with a reasonable basis in fact.

The argument rests upon a fundamental misconception about how the Vaccine Act works, and it fails to take into account the fact that statute of limitations issues are themselves inextricably intertwined with the merits of a vaccine petition — as this case amply demonstrates. This may help explain why, while the Secretary raises the specter of "shadow trials" repeatedly in her Petition, the dissent below (which is the origin of the phrase) mentions it only once, and even then only in passing.

ARGUMENT

1. The Court of Appeals' Decision Is Based Upon, And Fully Consistent With, The Plain Language Of The Vaccine Act.

The Vaccine Act's attorneys' fees and costs provision provides as follows:

> (1) In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover—
>
> (A) reasonable attorneys' fees, and
>
> (B) other costs, incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

42 U.S.C. 300aa-15 (e) (emphasis added).

On its face, the Act provides for the payment of

attorneys' fees and costs "incurred in any proceeding" related to "a petition filed under section 300aa-11", including in cases where no compensation is awarded to the petitioner. Thus, the Secretary correctly observes that "the court of appeals' decision in this case depends on the court's determination that an untimely Vaccine Act petition is a 'petition filed under [42 U.S.C. 300aa-11]." Petition at 11 (bracketed text in original).

Section 300aa-11 provides, in relevant part, that "[a] proceeding for compensation under the [Vaccine] Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) of this section with the United States Court of Federal Claims." 42 U.S.C. §300aa-11 (a) (1) (emphasis added). Section (a) (1) says nothing about compliance with the Act's statute of limitations in section 300aa-16 being a prerequisite for initiating "a proceeding" under the Act.

Thus, and by its plain terms, if a petition is filed and served upon the Secretary, and if it contains the matters required by subsection (c), then "a proceeding for compensation" has been initiated under the Act. And, accordingly, attorneys' fees incurred in connection with that proceeding may be paid pursuant to section 300aa-15 (e) (1).

In contrast to section 300aa-11 (a) (1), section 300aa-11 (a) (2) (A) prohibits a petitioner from bringing a civil action in State or Federal court arising from a vaccine-related injury "unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program . . ." Section 300aa-11

(a) (2) (A) makes clear that Congress knew how to condition the provisions of section 300aa-11 upon compliance with the Act's statute of limitations provision contained in section 300aa-16.

Congress required compliance with the statute of limitations before a plaintiff could file a civil suit pursuant to section 300aa-11 (a) (2) (A), but Congress did not require such compliance as a precondition to initiating a proceeding for compensation pursuant to 300aa-11 (a) (1). Thus, while Congress specifically conditioned the right to file a civil suit on the filing of a timely petition under section 300aa-16, Congress did not condition the availability of attorneys' fees upon the filing of a timely petition under that same section 300aa-16.

Thus, the Circuit en banc majority correctly concluded that because section 300aa-15 (e) (1) permits an award of attorneys' fees incurred in connection with "any proceedings" brought pursuant to 300aa-11, and because neither section 300aa-15 (e) (1) nor section 300aa-11 (a) (1) requires compliance with the Act's statute of limitations provision as a precondition to initiating proceedings under the Act, compliance with section 300aa-16 is not a prerequisite to reimbursement for attorneys' fees and costs under the Act. App. at 5a-9a[2].

Nevertheless, the Secretary insists that the failure of Congress to mention the Act's statute of limitations in

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[2]Citations to the opinions below are to the appendix accompanying the Secretary's Petition.

either section 300aa-15 (e) (1) or 300aa-11 (a) (1) is of no consequence because the statute of limitations itself provides that "no petition may be filed for compensation under the Program" after its expiration. Petition at 11 (discussing §300aa-16 (a) (2)). Thus, the Secretary's argument goes:

> The fee-shifting provision requires "a petition filed under section [42 U.S.C.] 300aa-11 of this title," . . . and the limitations provision states that "no petition may be filed for compensation under the Program" after the expiration of prescribed time periods. . . . The fee-shifting provision's requirement of "a petition filed under [42 U.S.C.] 300aa-11" thus obviates the need for any direct cross-reference to the limitations provision itself.

Petition at 19 (internal citations omitted; bracketed language in original).

The problem with the Secretary's argument, and the reason it must be rejected, is that some provisions of section 300aa-11 do explicitly require compliance with the statute of limitations, whereas others do not. Compare §300aa-11 (a) (1) with §300aa-11 (a) (2) (A). Consequently, there is no way to reconcile the Secretary's reading of section 300aa-11 (a) (1) with the language used in section 300aa-11 (a) (2) (A), which requires that a "petition has been filed, in accordance with section 300aa-16 of this title." According to the Secretary, the first clause ("a petition has been filed") necessarily means a petition that has been filed in accordance with section 300aa-16. Thus, to accept the

Secretary's interpretation of the Act would render Congress's use of the second clause ("in accordance with section 300aa-16 of this title") utterly superfluous, in violation of firmly-established canons of statutory construction. *See, e.g., TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (noting "cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant") (internal quotations omitted); *United States v. Menasche*, 348 U.S. 528, 538-539 (1955) ("[i]t is our duty 'to give effect, if possible, to every clause and word of a statute'") (quoting *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883)).

Similarly, to accept the Secretary's statutory interpretation would render use of the phrase "in accordance with section 300aa-16" in section 300aa-11 (a) (2) (A), and the decision of Congress to omit that clause in section 300aa-11 (a) (1), a drafting choice of no significance and of no consequence, also in violation of well-settled canons of statutory construction. *See, e.g., Bates v. United States*, 522 U.S. 23, 29-30 (1997) ("where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion") (citing *Russello v. United States*, 464 U.S. 16, 23 (1983)).

2. The Secretary's Concerns About Collateral "Shadow Trials" Are Irrelevant And Wrong.

The majority of the Secretary's Petition is devoted to a discussion about the purported, and utterly

speculative, practical difficulties that might result from the Federal Circuit's decision in this case. Petition at 12-16, 23-25. The Secretary warns that a vaccine injury petition filed after the statute of limitations has run "may be dismissed on threshold grounds without any meaningful analysis of the merits," requiring special masters "to conduct a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding." Petition at 13 (internal quotations omitted). The problem, according to the Secretary, is that "[s]uch proceedings would typically include review of the claimant's medical records, development of expert testimony, and briefing to the special master." Ibid. The Secretary despairs: "Such a collateral proceeding would be wasteful, painful, and complex — the antithesis of the system that Congress designed to work faster and with greater ease than the civil tort system." Ibid. (internal quotations omitted).

The Secretary's concerns are irrelevant for two reasons. First, the sort of policy considerations identified by the Secretary furnish no basis for ignoring the plain language of the Vaccine Act. *See, e.g., Hartford Underwriters Ins. Co. v. Union Planters Bank, N. A.*, 530 U.S. 1, 6 (2000) ("when the statute's language is plain, the sole function of the courts-at least where the disposition required by the text is not absurd — is to enforce it according to its terms") (internal quotations omitted); *Tyler v. Cain*, 533 U.S. 656, 663, n.5 (2001) ("even if we disagreed with the legislative decision to establish stringent procedural requirements for retroactive application of new rules, we do not have license to question the decision on policy grounds").

Second, whatever practical concerns there might be with determining whether a time-barred claim was brought in good faith or with a reasonable factual basis, those are not concerns that arise in this case. As the Federal Circuit correctly observed, "the government does not dispute the reasonableness of Dr. Cloer's underlying claim or allege that it was not brought in good faith". App. 9a. Indeed, as the Chief Special Master noted in his May 15, 2008 decision, the evidence furnished in support of Dr. Cloer's petition were not disputed by the Secretary. App. 157a ("[t]he facts presented in this matter are uncontested").

In addition to being irrelevant, the Secretary's policy concerns are wrong in that they simply cannot be reconciled with the way the Vaccine Act works in practice. First, one has to bear in mind the distinction between "Table" and "non-Table" injuries. If a claimant has suffered a Table injury within a specified time frame after receiving a vaccine, the claimant is presumed to be entitled to relief under the Vaccine Act. *See, e.g.*, §§300aa-11 (c) (1) (C) (ii); 300aa-14; *Grant v. Secretary of HHS*, 956 F.2d 1144, 1147 (Fed.Cir.1992). Thus, in the case of a petition involving a Table injury where the claim is denied on statute of limitations grounds, virtually the only question to be answered on a compensation claim for attorneys' fees will be whether there was a good faith basis for arguing either that the statute of limitations had been complied with or that noncompliance should have been excused on the basis of equitable tolling. In all such cases, the special master will necessarily have to consider the facts underpinning the Secretary's statute of limitations argument in order to determine that the claim is time barred. Thus, no additional or burdensome "shadow trial" will be required

to determine whether the claimant nevertheless had a good faith or reasonable factual basis for bringing her petition outside of the limitations period: The facts and law that will have to be considered in ruling that a claim is time-barred will be identical to the facts and law that will have to be considered in determining whether the petition nevertheless was brought in good faith or with a reasonable basis in fact.

Second, and in the case of non-Table injuries, the dichotomy that underlies the Secretary's "shadow trial" argument — where statute of limitations determinations are portrayed as being entirely separate and distinct from an analysis of the merits of a claim — simply does not exist. In order to recover for a non-Table injury, a claimant is required to prove "cause in fact", to wit, that her injury was caused by a previously-administered vaccine. *See, e.g.*, § 300aa-11 (c) (1) (C) (ii); *Grant,* 956 F.2d at pp. 1147-48. In order to evaluate whether a petition has been filed within the applicable statute of limitations, the special master must determine whether a petition has been filed, "after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of [a vaccine-related] injury. § 300aa-16 (a) (2).

[1] In order to determine when the "first symptom" or "manifestation of onset" or "significant aggravation" of a vaccine-related injury occurred, the special master must necessarily determine what that injury is, whether it was caused by a vaccine, and what its symptoms, manifestations and/or aggravations are. The special master must then determine what the facts of a particular case say about each of those things. All of

which is to say: In order to determine when the statute of limitations on a particular claim has expired, one must consider in detail the facts underlying the merits of that claim, as Dr. Cloer's case itself amply demonstrates.

The chief special master's decision dismissing Dr. Cloer's petition correctly noted that "the sole issue presented at this stage of the proceedings is whether Dr. Cloer's Petition . . . was filed within '36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.' § 300-aa-16 (a) (2)." App. at 157a. And yet, the Decision went into minute detail about the nature of Dr. Cloer's injury, her medical history and diagnosis, the expert testimony submitted in support of her petition and host of other matters. See App. 157a-164a, 168a-173a. It was only "[a]fter considering the entire record and the parties' respective arguments", that the chief special master was in a position to conclude that "this case must be dismissed as untimely." App. 168a. Why? Because, as the special master explained, "the medical records, petitioner's affidavits, as well as Dr. Meyer's affidavits and testimony [established] that the first symptom of the onset of Dr. Cloer's [injury] was in 1997." *Ibid.*

The Secretary fears that "[p]roceedings to decide whether there was a reasonable basis for a claim (had it been timely) would consume much of the effort that actually deciding the claim would have entailed, undermining the resource-conserving purpose of the limitations provisions [because s]uch proceedings would typically include review of the claimants medical records, development of expert testimony, and briefing to

the special master." Petition at 13.

As this case demonstrates, that fear is unfounded: "[M]uch of the effort that actually deciding the claim would have entailed" was in fact required in order to rule upon the Secretary's own claim that Dr. Cloer's petition was barred by the statute of limitations, including "review of the claimant's medical records, development of expert testimony, and briefing to the special master[3]." Even more examination of the merits will take place in the examination of equitable tolling, as required by the new doctrine announced below.

Third, and for similar reasons, there is no merit to the Secretary's claim (Petition at 14) that these "shadow trial[s] would be thoroughly unappealing to the claimant herself" because they will require "the claimant to further expose her medical records (and perhaps herself) to expert examination . . . [while] produc[ing] no tangible benefit for the claimant herself, only for her lawyer." As the Secretary well knows, the Vaccine Act provides that all petitions "shall contain," among other things, "maternal prenatal and delivery records, newborn

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[3]Curiously, the Secretary cites *Smith v. Secretary of HHS*, 2006 WL 5610517 (Fed. Cl. July 21, 2006), as a case that "aptly illustrates the problem the court of appeals' decisions creates." Petition at 15. But the Secretary's own discussion of the case illustrates the fact that, in order to conclude that Smith's petition was barred by the statute of limitations, the special master was required to carefully evaluate the facts underlying Smith's petition. Thus, just as occurred in this case below, the special master's statute of limitations rulings in *Smith* required an intimate familiarity with the facts of the case. Asking the special master to determine whether those facts furnished a reasonable basis for filing Smith's petition is not too much to ask.

hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results . . ." 42 U.S.C. §300aa-11 (c) (2).

Thus, it is not a request for payment of fees that "expose[s a claimant's] medical records," as the Secretary claims, it is the very fact of filing a petition that does so. As far as the Secretary's assertion that a claim for fees sought in connection with a petition that denies compensation provides no "tangible benefit to the claimant herself, only her lawyers," it is enough to say that all potential claimants benefit from the existence of a qualified bar willing to bring claims under the Vaccine Act even when the success of those claims is not guaranteed. The fees and costs scheme of the Act is designed "to ensure that vaccine-injury claimants will have readily available a competent bar to prosecute their claims under the Act." *Saunders v. Secretary of HHS*, 25 F.3d 1031, 1035 (Fed.Cir.1994). *See also Perdue v. Kenny A. ex rel. Winn*, 130 S. Ct. 1662, 1672 (2010) (fees must be "sufficient to induce a capable attorney" to undertake a case).

Fourth, the Secretary warns that the Federal Circuit's decision "is likely to increase the number of untimely Vaccine Act petitions" which will "impede the prompt resolution of meritorious claims for much-needed compensation." Petition at 24-5. The Secretary acknowledges that this fear is entirely speculative (id. at

24), and this hardly furnishes the sort of "consequences [that] are sufficiently serious to warrant this Court's intervention," as the Secretary asserts. *Id.* at 23.

3. The Canons Of Statutory Construction Cited By The Secretary Furnish No Support For Her Interpretation Of The Act.

The Secretary argues that her interpretation of the Vaccine Act finds additional support in the notion that, "the scope of the Vaccine Act's waiver of sovereign immunity — including the United States' liability to pay respondent's attorneys' fees and costs — should be strictly construed." Petition at 7. However, this rule of "strict construction" is but one canon of statutory construction, and it is not implicated where, as here, traditional canons of statutory construction (like those discussed in Part 1 above) resolve any purported statutory ambiguity. *Richlin Sec. Service Co. v. Chertoff*, 553 U.S. 671, 590 (2008) ("[T]raditional tools of statutory construction and considerations of stare decisis compel the conclusion that paralegal fees are recoverable as attorney's fees at their prevailing market rates. There is no need for us to resort to the sovereign immunity canon because there is no ambiguity left for us to construe.") (internal citations and quotations omitted).

Moreover, it is questionable whether the Vaccine Act involves a true waiver of sovereign immunity to being with. This Court has long recognized that traditional rules involving sovereign immunity are "inapplicable where the Government has cast off the cloak of sovereignty and assumed the status of a private commercial enterprise." *Library of Congress v. Shaw*, 478 U.S. 310, 321 (1986) (citing *Standard Oil Co. v.*

United States, 267 U.S. 76, 79 (1925)). The Vaccine Act establishes a consumer-funded insurance system that replaces traditional civil tort actions against manufacturers of covered vaccines. *See* Joint Committee on Taxation, Issues Arising in the Determination of an Appropriate Funding Source for The National Childhood Vaccine Injury Program (JCS-4-87), March 4, 1987 at 2 (explaining that the Vaccine Act program was created "as an alternative source of compensation to civil tort actions against manufacturers of the prescribed vaccines .... [and] substitutes a Federal insurance system for the existing State-law tort and private insurance system") (emphasis added).

Moreover, such compensation funds are "treated as a trust fund" and have "the same characteristics as any insurance carrier." Lee R. Russ & Thomas F. Segalla, *Couch on Insurance* §10:12 (3d ed.1995). As such, "[i]t is common that pursuant to such statutes the fund . . . will not be entitled to sovereign immunities that would not be afforded to private insurance carriers." *Ibid. See Standard Oil Co.*, 267 U.S. at 79 ("[w]hen the United States went into the insurance business, issued policies in familiar form and provided that in case of disagreement it might be sued, it must be assumed to have accepted the ordinary incidents of suits in such business"). *Compare Sandia Oil. Co. v. Beckton*, 889 F.2d 258, 263-64 (10th Cir.1989) (holding that FEMA's flood insurance program was not a "commercial enterprise" defeating claims of sovereign immunity because, "[t]he flood insurance program was intended from the beginning to be, not a commercial enterprise, but rather a subsidized insurance program . . . designed to accomplish important national goals at some cost to the national treasury") (emphasis added).

The Secretary also argues that courts should show "particular hesitation" before concluding that the Vaccine Act permits the payment of fees incurred in connection with time-barred claims because the Vaccine Act's "remedial provisions" will "expose[] the United States to much more expansive potential fee liability". Petition at 18-19. This claim is doubly wrong.

The Act's remedial nature does not counsel hesitation and strict construction, it mandates a liberal construction. *See, e.g., United States v. An Article of Drug*, 394 U.S. 784, 798 (1969) (recognizing "the well-accepted principle that remedial legislation . . . is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health")[4]. Second, and as noted above, no payments made under the Vaccine Act — whether payments for compensation to an injured petitioner or the payments of attorneys' fees and costs — create any true "liability" to the United States. See, infra, footnote 1. The United States merely administers a Trust Fund that is privately funded in its entirety. And to any extent the Secretary is suggesting that the payment of attorneys' fees incurred in connection with time-barred petitions brought in good faith might jeopardize the solvency of the fund, the claim is absurd[5].

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[4]The majority below noted this same important doctrine, that remedial legislation should be "construed in a manner that effectuates its underlying reason and purpose. App at 8a (citing *Atchison, Topeka and Santa Fe Ry. Co. v. Buell*, 480 U.S. 557, 561-62 (1987)).

[5] As noted, the Trust Fund established under the Act is well funded. *See, infra*, footnote 1. In addition, while the Secretary seems to fear a flood of litigation involving time-barred claims brought by lawyers enticed by the promise of recovering their fees and costs, that fear is not well founded. The

(continued...)

Third, and finally, the Secretary argues "that ambiguous language in federal fee-shifting provisions should be construed . . . to limit the length and complexity of fee litigation," and in support, the Secretary cites a case in which this Court adopted a deferential standard of review of a district courts' fee determinations in order to purse that objective. Petition at 18 (citing *Pierce v. Underwood*, 487 U.S. 552, 563 (1988)). Although the Secretary hazards no opinion about the standard of review that should be applied to fee determinations under the Vaccine Act, the Secretary asserts that the principle of *Pierce* "is directly applicable here." Petition at 18. But, the Secretary cites no authority, and Dr. Cloer is aware of none, that supports the idea that the payment of attorneys' fees should be precluded as a matter of law because doing so has the virtue avoiding the "complexity" involved in determining what the amount of such awards should be.

CONCLUSION

The Federal Circuit's ruling that the Vaccine Act permits the payment of attorneys' fees incurred in any proceedings brought under the Act, including

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(...continued)

Federal Circuit's decision makes clear that both a claim for compensation and arguments about the timeliness of a claim must be brought in good faith and with a reasonable basis in fact. App. at 5a. And, to the extent the Secretary's fear is premised upon the opportunities created by the Federal Circuit's earlier recognition that equitable tolling is available under the Act, we note simply that the availability of equitable tolling is, according to the Circuit, exceptionally limited. App. at 65a-66a (concluding that Dr. Cloer's petition was not subject to equitable tolling because she had made no showing that, "she has been the victim of a fraud, or of duress" and noting that its holding "sharply limits" the ability to bring time-barred claims under the Act).

proceedings where no award of compensation is made because a petition is deemed to be time barred, is correct and consistent with the plain language of the Act. There is no reason for this Court to review that decision.

Moreover, even if the Federal Circuit's decision could create the practical difficulties envisioned by the Secretary, this Court has no reason to review this case, which presents none of them. The merits of Dr. Cloer's petition were not contested below by the Secretary.

The Secretary's Petition should be denied.

Respectfully submitted, October, 2012

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REPLY BRIEF

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No. 12-236

In the Supreme Court of the United States

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

MELISSA CLOER

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

The sharply divided en banc court of appeals held that a claimant whose petition under the National Vaccine Injury Compensation Program (Compensation Program) is dismissed as untimely may recover from the United States an award of attorneys' fees and costs. As the petition for certiorari explains, that holding is inconsistent with the text of the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), 42 U.S.C. 300aa-1 *et seq.*, and it runs contrary to the applicable canons of statutory construction. The decision below also promises to spawn burdensome collateral fee proceedings that are entirely out of place in the streamlined compensation system that the Act promises. Respondent offers only the barest of arguments in support of the court of appeals' decision, and she wholly fails to refute our showing that the decision threatens the efficient

functioning of the Compensation Program. The petition for a writ of certiorari should be granted to correct the court of appeals' serious error.

A. Respondent's Sole Textual Argument In Support Of The Court Of Appeals' Ruling Is Unpersuasive

Respondent acknowledges that the relevant textual question in this case is whether "an untimely Vaccine Act petition is a petition filed under 42 U.S.C. 300aa-11." Br. in Opp. 5 (quoting Pet. 11) (internal quotation marks and brackets omitted). As the certiorari petition explains (at 11), an untimely Vaccine Act petition is not "a petition filed" under that section because the limitations provision says it is not: "*no petition may be filed* for compensation under the Program" after the expiration of the applicable time period. 42 U.S.C. 300aa-16(a)(2) (emphasis added).

In contesting this straightforward reading of the Vaccine Act, respondent relies solely (Br. in Opp. 6-8) on the fact that 42 U.S.C. 300aa-11(a)(2)(A) (which addresses the circumstances under which a civil action may be filed after proceedings under the Compensation Program have concluded) expressly cross-references the limitations provision, while 42 U.S.C. 300aa-11(a)(1) (the provision for initiating a compensation proceeding) and 42 U.S.C. 300aa-15(e)(1) (the attorneys' fees and costs provision) do not. Respondent infers from that distinction that Congress must have intended the first of those provisions, but not the second or third, to depend on compliance with the limitations provision. That inference is unfounded.

To begin with, respondent's argument proves too much. Section 300aa-11(a)(2)(A) is one of only a handful of provisions in the Vaccine Act with an express cross-reference to the limitations provision. If an express

cross-reference to the limitations provision were needed to trigger its application, the provision would be irrelevant in a broad array of circumstances. On respondent's logic, for example, a failure to comply with the limitations provision would not even bar recovery under the Compensation Program itself because 42 U.S.C. 300aa-13 ("Determination of eligibility and compensation") does not expressly cross-reference the limitations provision. No such problems arise, and the court of appeals' error becomes clear, when the limitations provision and other provisions of the Vaccine Act are read as the government urges. See Pet. 19-20.

Respondent is also mistaken in contending that, other than her reading, "there is no way to reconcile" (Br. in Opp. 7) the express cross-reference in Section 300aa-11(a)(2)(A) with the absence of a similar cross-reference in other provisions. The various provisions respondent points to are written differently because they serve different functions. Unlike the other provisions respondent cites, Section 300aa-11(a)(2)(A) establishes a prerequisite to specified suits "in a State or Federal court." The express cross-reference to the Vaccine Act's limitations provision demonstrates that preemption of any contrary state-law rule governing the same question was "the clear and manifest purpose of Congress." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). In any event, Congress often employs language "out of an abundance of caution" and "to remove any doubt" on an issue." *Ali* v. *Federal Bureau of Prisons*, 552 U.S. 214, 226 (2008) (quoting *Fort Stewart Sch.* v. *FLRA*, 495 U.S. 641, 646 (1990)). At a minimum, the court of appeals' interpretation of the Vaccine Act is not so "plain" (Br. in Opp. 9) that this Court should ignore the canons of construction (see pp. 4-5, *infra*) and structural features of

the statute (see pp. 6-11, *infra*) that cut so sharply against that interpretation and in favor of the government's reading.

B. Applicable Canons Of Statutory Construction Support The Government's Interpretation, And Respondent's Contrary Arguments Lack Merit

As the certiorari petition explains (at 16-19), three relevant canons of statutory construction confirm that the Vaccine Act does not permit an award of attorneys' fees and costs on an untimely petition. Respondent entirely fails to address one of those canons—that the Vaccine Act's fee-shifting provision departs so significantly from background principles that a court "should be cautious in interpreting the statutory mandate to extend beyond those cases in which fee-shifting was clearly intended," Pet. App. 19a (Bryson, J., dissenting). With respect to another canon, respondent states that she knows of "no authority * * * that supports the idea that the payment of attorneys' fees should be precluded * * * [to] avoid[] the complexity involved in determining * * * such awards." Br. in Opp. 18 (internal quotation marks omitted). But this Court has made clear that, as between an interpretation of a fee-shifting statute that will "result in a second major litigation" and one that will not, the latter is to be preferred. *Hensley* v. *Eckerhart*, 461 U.S. 424, 437 (1983).

Finally, in response to the government's invocation of the principle that the scope of a waiver of sovereign immunity should be strictly construed, respondent "question[s] whether the Vaccine Act involves a true waiver of sovereign immunity to be[gin] with." Br. in Opp. 15. Respondent relies on the fact that excise taxes paid on each dose of a covered vaccine (26 U.S.C. 4131) are deposited into the Vaccine Injury Compensation

Trust Fund (Compensation Fund) in the Treasury (26 U.S.C. 9510) that is used to pay awards under the Compensation Program (42 U.S.C. 300aa-15(f)(4)(A)). Respondent contends that, because this framework could be analogized to commercial insurance premiums paid into a fund used by the insurer to pay claims, sovereign immunity principles do not apply to the Compensation Fund.

That argument is misconceived because the Compensation Program is not commercial insurance. Rather—as with many federal programs that involve federal funds and are subject to principles of sovereign immunity—the Compensation Program raises money through Congress's "Power To lay and collect * * * Excises," U.S. Const. Art. I, § 8, Cl. 1; the Treasury holds that money for the benefit of the United States; and funds are disbursed to claimants to "provide for the * * * general Welfare of the United States," *ibid.* The status of the Compensation Program as a waiver of sovereign immunity is confirmed by the statutory requirement that any suit for compensation under the Program be filed against the Secretary of Health and Human Services in her official capacity. 42 U.S.C. 300aa-12(b)(1); see Pet. 3, 16. The Compensation Program's structure is thus thoroughly distinguishable from the "policies of insurance issued by the Government" at issue in *Standard Oil Co.* v. *United States*, 267 U.S. 76, 76 (1925), the case on which respondent relies (see Br. in Opp. 15-16).[1]

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[1] To the extent that respondent relies on the label "Trust Fund" (see Br. in Opp. 1 n.1, 16) to suggest that the Compensation Fund is different from most other federal funds, she is mistaken. Like the Compensation Fund, many dedicated funds in the Treasury bear the formal label of "Trust Fund," see, *e.g.*, 26 U.S.C. Ch. 98, Subch. A

C. Respondent Offers No Sound Reason To Doubt That The Court Of Appeals' Decision Will Have Significant Adverse Consequences For The Compensation Program

As the six dissenting judges below explained, because Vaccine Act fees are available only for petitions brought in good faith and with a reasonable basis, a special master addressing a fee request for a petition dismissed as untimely would be required to conduct "a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding." Pet. App. 20a. The petition for certiorari explains (at 12-16) how complex, wasteful, burdensome, and unpleasant such shadow trials could be. The profound mismatch between those shadow trials

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("Establishment of Trust Funds"), but such funds are generally an accounting and appropriations mechanism, and very few are actually held *in trust* for someone other than the United States. See, *e.g.*, *Flemming* v. *Nestor*, 363 U.S. 603, 608-611 (1960) (holding that an individual did not have a vested right to receive certain Social Security benefits from the Federal Old-Age and Survivors Insurance Trust Fund, 42 U.S.C. 401(a)); GAO, *Federal Trust and Other Earmarked Funds: Answers to Frequently Asked Questions* 7 (Jan. 2001) ("In the federal budget the meaning of the term 'trust' differs significantly from its private sector usage. * * * [I]n contrast to a private trust fund, the federal government does not have a fiduciary responsibility to the trust beneficiaries, and it can raise or lower future trust fund collections and payments or change the purposes for which the collections are used by changing existing laws. Moreover, the federal government has custody and control of the funds."), http://gao.gov/assets/210/200562.pdf; Off. of Mgmt. & Budget, *Analytical Perspectives: Budget of the U.S. Government* 133 (FY 2013) ("*Trust funds* account for the receipt and expenditure of monies by the Government for carrying out specific purposes and programs in accordance with the terms of a statute that designates the fund as a trust fund (such as the Highway Trust Fund)."), http://www.whitehouse.gov/sites/default/files/omb/budget/fy2013/assets/spec.pdf.

and the Vaccine Act's compensation system "designed to work faster and with greater ease than the civil tort system," *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011) (quoting *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995)), both signals that the decision below is incorrect and highlights a fundamental programmatic distortion that warrants correction by this Court.

1. Respondent acknowledges that a fee award on an untimely petition would necessitate the determinations that the dissent below foresaw being made in shadow trials. See Br. in Opp. 17 n.5 (citing Pet. App. 5a). Respondent contends, however, that such proceedings will not in practice be necessary or burdensome. Respondent's arguments are unpersuasive.

First, respondent contends that, "in the case of a petition involving a Table injury where the claim is denied on statute of limitations grounds, virtually the only question to be answered on a compensation claim for attorneys' fees will be whether there was a good faith basis for arguing [that the claim was timely]." Br. in Opp. 10.[2] But that begs the central question whether the claimant had a reasonable basis for asserting that an injury falls within the parameters of the Table. That issue is often disputed in claims adjudicated on the merits, and it similarly would be the subject of a shadow trial when a putative Table claim is dismissed as untimely.

An apt example is the Vaccine Act proceeding that preceded the civil litigation that culminated in this

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[2] Under the Act, causation is rebuttably presumed when the claim is based on an injury specified in the Vaccine Injury Table, while the claimant must establish causation if the claim for injury falls outside the parameters of the Table. See Pet. 3. The former are often referred to as "Table claims" and the latter as "non-Table claims."

Court's decision in *Bruesewitz*. There, the vaccine recipient suffered seizures and claimed, *inter alia*, to have suffered an acute encephalopathy (a Table injury for the vaccine in question). After extensive testimony and analysis of her medical records revealed that the claimant was alert and active between seizures (behavior inconsistent with a diagnosis of acute encephalopathy), the special master rejected the Table claim. *Bruesewitz* v. *Secretary of HHS*, No. 95-266V, 2002 WL 31965744, at *12 (Fed. Cl. Dec. 20, 2002). If the Vaccine Act claim in *Bruesewitz* had been rejected as untimely, similar testimony and analysis would have been required to determine whether there was a reasonable basis for a Table claim.

Second, respondent posits that no further effort will be required to decide whether an award of attorneys' fees and costs is appropriate after a petition is dismissed as untimely because "to determine when the statute of limitations on a particular claim has expired, one must consider in detail the facts underlying the merits of that claim." Br. in Opp. 12. At least in the usual case, however, the very nature and purpose of a limitations defense is that it *avoids* inquiry into the substance of a plaintiff's claim. See, *e.g.*, *Ritchey* v. *Upjohn Drug Co.*, 139 F.3d 1313, 1319 (9th Cir.), cert. denied, 525 U.S. 963 (1998). The threshold limitations decision therefore ordinarily will be uninformative on the question whether there was a reasonable basis for the claim on the merits.

Typically, a special master conducting a limitations analysis need only determine "the date of the occurrence of the first symptom or manifestation of onset" of the claimed injury. 42 U.S.C. 300aa-16(a)(2). In respondent's case, "[t]he sole issue presented" to the special master concerned the date of respondent's first

symptom of multiple sclerosis (MS). Pet. App. 157a; see *id.* at 168a. The parties did not litigate, and the special master was not called upon to decide, whether there was a reasonable basis for believing that a Hepatitis-B immunization caused respondent's MS. The same will be true of any other non-Table claim dismissed as untimely; the question whether the claimant's injury was caused by a vaccine will call for evidence and expertise quite different from that required to decide when the injury first manifested.[3]

Third, respondent contends (Br. in Opp. 13-14) that, because 42 U.S.C. 300aa-11(c)(2) already requires a petition for compensation to include the claimant's medical records, a shadow trial will not be an additional burden on the claimant. But the potential burden on a claimant and her family often goes beyond the mere submission of records. See, *e.g.*, *Bruesewitz*, 2002 WL 31965744, at *8 (discussing testimony by vaccine recipient's parents). And even as to medical records, when a petition for compensation is dismissed as untimely, subsequent fee proceedings will require *further* scrutiny of those records by causation experts on both sides of the case, for an opinion on whether the claimant's injury was caused by a vaccine, all with no possibility of producing a tangible benefit for the claimant. See Pet. 14. And in any event, respondent's contention fails to address the

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[3] Respondent's assertion that the timeliness inquiry will turn on "whether [a claimant's injury] was caused by a vaccine," Br. in Opp. 11, is particularly unfounded. The panel below held that limitations and causation issues were intertwined such that medical recognition of a causal link was a prerequisite to the running of the limitations period. Pet. App. 95a-102a. The en banc court overruled the panel on precisely that point, however, see *id.* at 51a-57a, and this Court denied respondent's petition for a writ of certiorari seeking further review of that issue, 132 S. Ct. 1908 (2012) (No. 11-832).

larger problem that, under the decision below, the Compensation Program's resources must be diverted away from adjudicating claims for compensation on the merits, and toward conducting shadow trials to decide attorneys' fee applications in untimely cases.

2. Respondent asserts that the prospect of shadow trials is "utterly speculative," Br. in Opp. 8-9, but she fails to identify anything conjectural about the government's concerns. All agree that some Vaccine Act petitions are dismissed as untimely. The decision below holds that an award of attorneys' fees and costs is nonetheless available for such petitions. The availability of such an award in a particular case is contingent on particular findings about the hypothetical merits of the underlying claim, but those findings will not be evident from a proceeding that has considered only when the claimant's injury first manifested. Some collateral proceeding for making those findings will therefore be required, and that proceeding will entail the same type of inquiry that actually deciding the claim would have involved. The practical consequences of the decision below are so apparent that not even the en banc majority disputed them; the only point of disagreement below was whether Congress intended those consequences.

Moreover, as the petition for certiorari explains (Pet. 24-25), the inducement of a fee award to claimants' counsel is likely to increase the number of untimely Vaccine Act petitions, further distorting the Compensation Program. Respondent contends (Br. in Opp. 17 n.5) that the limitation of fee awards to petitions that had a reasonable basis on the merits will keep this unproductive incentive in check. But an untimely petition that advances a reasonable position on the merits is still untimely, and it fails to advance the Vaccine Act's goal

of delivering compensation to those entitled to it. Respondent also notes that "the availability of equitable tolling is * * * exceptionally limited." *Ibid.* If anything, that fact underscores the government's concerns because it increases the likelihood that claimants will advance reasonable but unsuccessful tolling arguments, leading to swiftly denied claims for compensation, followed by extended fee proceedings to assess the reasonableness of the claimant's (hitherto unadjudicated) arguments for relief on the merits. Diversion of the Compensation Program's resources to those collateral proceedings is inconsistent with the Vaccine Act's text and would disserve Congress's objectives.

* * * * *

For the foregoing reasons and those stated in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted.

DONALD B. VERRILLI, JR.
Solicitor General

NOVEMBER 2012

JOINT APPENDIX

Supreme Court, U.S.
FILED
JAN 4 - 2013
OFFICE OF THE CLERK

No. 12-236

In the Supreme Court of the United States

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

MELISSA CLOER

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

JOINT APPENDIX

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PETITION FOR A WRIT OF CERTIORARI FILED: AUG. 22, 2012
CERTIORARI GRANTED: NOV. 20, 2012

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The following opinions and orders have been omitted in printing this joint appendix because they appear on the following pages in the appendix to the petition for a writ of certiorari:

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Appendix E:	Court of Federal Claims opinion and order (Nov. 25, 2008)	126a
Appendix F:	Decision of the special master (May 15, 2008)	155a

UNITED STATES COURT OF FEDERAL CLAIMS

Docket No. 05-VV-1002

MELISSA CLOER, M.D., PETITIONER-APPELLANT

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

DOCKET ENTRIES

DOCKET NUMBER	PROCEEDINGS
1	Appeal docketed on 03/09/2009 EOD (03/09/2009 by CLT) 2009-5052
	* * * * *
9	Appellant [Melissa Cloer, M.D.]—Unopposed motion for an extension of time, of 32 days, within which to file an opening brief. Mail Service—04/03/09 Filed: 05/01/09. On consent. Action on Motion (10): Granted. Brief is due on or before 6/9/09, by Clerk. Filed: 05/01/09. EOD (05/01/09 by SJ) 2009-5052
	* * * * *

DOCKET NUMBER	PROCEEDINGS
13	Melissa Cloer, M.D. [Appellant]—Brief for Petitioner-Appellant. Mail Service—06/09/09. Filed: 06/09/09. REV (06/09/09 by VW) 2009-5052
14	Secretary of Health and Human Services [Appellee]—Brief of Respondent-Appellee Secretary of Health and Human Services. Mail Service—07/22/09. Filed: 07/22/09. REV (07/23/09 by JS) 2009-5052
15	Melissa Cloer, M.D. [Appellant]—Reply Brief for Petitioner-Appellant. Mail Service—08/10/09. Filed: 08/10/09. REV (08/11/09 by VW) 2009-5052
16	Melissa Cloer, M.D. [Appellant]—Joint Appendix. Mail Service—08/17/09. Filed: 08/17/09. REV (08/19/09 by SEW) 2009-5052
17	NOTICE OF CALENDARING issued. Panel: 0911N on November 4, 2009. Entered: 09/21/2009. (EOD 09/22/2009 by KSH) 2009-5052

* * * * *

DOCKET NUMBER	PROCEEDINGS
20	Submitted after ORAL ARGUMENT by Mari C. Bush and Lynn E. Ricciardella Panel Michel, Clevenger and Dyk. Entered: 11/04/2009. (EOD 11/04/2009 by KSH) 2009-5052
21	Disposition: Reversed and Remanded by Panel. Precedential Opinion by: J. Michel. Dissenting Opinion By: J. Clevenger. Judgment Entered: 05/06/10. Costs against Appellant. Opinion sent to parties: 05/06/10. Filed: 05/06/10. EOD (05/06/10 by CLT) 2009-5052 [VACATED 10/25/10]
22	Appellee [Secretary of Health and Human Services]—Combined Petition for Panel Rehearing and Rehearing En Banc Mail Service—06/21/10. Filed: 06/21/10. Petition circulated: 06/22/10. Response requested from: Appellant (Melissa Cloer, M.D.). Response due: 07/22/10. Response filed: 07/22/10. Response circulated: 07/22/10. En Banc circulated: 09/02/10. Petition/En Banc Action (28): Denied/ Granted on 10/25/10. REV (10/25/10 by LB) 2009-5052

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DOCKET NUMBER	PROCEEDINGS
25	Appellant [Melissa Cloer, M.D.]—Unopposed Motion for Extension of Time to File Petitioner-Appellant's Response to the Combined Petition for Rehearing and Rehearing En Banc. Mail Service—07/02/10. Filed: 07/02/10. On consent. Action on Motion (27): Granted. Appellant may file a response to the combined petition for rehearing by 07/22/2010 by Merits Panel. Filed: 07/07/10. EOD (07/06/10 by LB) REV (07/07/10 by LB) 2009-5052
	* * * * *
29	ORDERED: (1) The petition for panel rehearing is denied; (2) the petition for rehearing en banc is granted; (3) the court's May 6, 2010 opinion is vacated, and the appeal is reinstated; (4) the parties are requested to file new briefs (con't). Court Service—10/25/10. Mailed: 10/25/10 REV (10/25/10 by LB) 2009-5052
30	(con't from entry #29) See order for details regarding the issues to be briefed, filing requirements, and participation by amici curiae. En Banc. PER CURIAM. No Service Required. Entered: 10/25/10. REV (10/25/10 by LB) 2009-5052

DOCKET NUMBER	PROCEEDINGS
31	Reinstated: 10/25/10 REV (10/25/10 by LB) 2009-5052
32	NOTE TO FILE: Originally filed Brief of Respondent-Appellee filed on July 22, 2009, received; original and thirty copies. Mail Service—07/22/09. Received: 11/02/10. REV (11/03/10 by VW) 2009-5052
33	NOTE TO FILE: The originally filed Brief for Petitioner-Appellant; Reply Brief for Petitioner-Appellant; and Joint Appendix received November 12, 2010 per the court's order dated October 25, 2010. No Service Required. Entered: 11/12/10. REV (11/12/10 by SEW) 2009-5052
34	Martin James Martinez [Amicus]—Amicus Brief. Mail Service—11/19/10. Received: 11/29/10. Rejected: 12/02/10. Corrected Brief Due: 12/09/10 REV (12/02/10 by C_C) 2009-5052

* * * * *

DOCKET NUMBER	PROCEEDINGS
36	Appellee [Secretary of Health and Human Services]—Unopposed Motion for 14-day extension of time to file respondent's supplemental en banc brief. Mail Service—12/02/10. Filed: 12/02/10. On consent. Action on Motion (37): The motion is granted. Appellee's en banc brief is due by December 23, 2010. Appellant is also granted a 14-day enlargement so that its response brief is due within 54 days of service of appellee's en banc brief by Court—En Banc Filed: 12/07/10. EOD (12/03/10 by JB) REV (12/07/10 by LB) 2009-5052
	* * * * *
41	Martin James Martinez [Amicus]—Corrected Brief of Amicus Brief. Mail Service—11/19/10. Filed: 12/20/10. REV (12/28/10 by VW) 2009-5052
42	Secretary of Health and Human Services [Appellee]—Supplemental En Banc Brief of Respondent-Appellee Secretary of Health and Human Services. Mail Service —12/23/10. Filed: 12/23/10. REV (12/28/10 by VW) 2009-5052
	* * * * *

DOCKET NUMBER	PROCEEDINGS
46	Melissa Cloer, M.D. [Appellant]—Supplemental En Banc Brief of Petitioner-Appellant. Mail Service—02/15/11. Filed: 02/15/11 REV (02/16/11 by C_C) 2009-5052
47	Appellee [Secretary of Health and Human Services]—Unopposed Motion for a 14-Day Extension of Time to File the Respondent's (HHS) Supplemental En Banc Reply Brief Mail Service—02/25/11. Filed: 02/25/11. Action on Motion (59): The motion is granted. Appellee may file a supplemental en banc reply brief by 3/21/11 by Court [ILLEGIBLE]
48	Other [National Vaccine Information Center]—Motion to Extend Time for Filing Brief of Amicus Curiae National Vaccine Information Center [NFP] Mail Service—02/25/11. Filed: 02/25/11. Action on motion (58): The motion is granted. NVIC may file a brief amicus curiae by 02/25/11 by Court—En Banc. Filed: 03/03/11. EOD (02/28/11 by LB) REV (03/03/11 by LB) 2009-5052 [Illegible]
02/25/11.	Filed: 02/25/11.. EOD (02/28/11 by LB) 2009-5052

* * * * *

DOCKET NUMBER	PROCEEDINGS
51	Colorado Trial Lawyers Association [Amicus]—Brief of Amicus Curiae Colorado Trial Lawyers Association in Support of Petitioner-Appellant in Favor of Petitioner-Appellant. Mail Service—02/22/11. Filed: 02/22/11. REV (02/28/11 by C_C) 2009-5052
	* * * * *
55	National Vaccine Information Center [Amicus]—Brief for Amicus Curiae National Vaccine Information Center In Support of Petitioner-Appellant. Mail Service —02/25/11. Filed: 02/25/11. REV (03/02/11 by SJ) 2009-5052
	* * * * *
60	Notice of Correction for Amicus Curiae The Vaccine Injured Petitioners Bar Association, et al. to correct Brief of Amicus Curiae submitted 2/22/2011. Mail Service —03/08/11. Filed: 03/08/11. REV (03/08/11) by C_C) 2009-5052
	* * * * *

DOCKET NUMBER	PROCEEDINGS
63	Vaccine Injured Petitioners Bar Association, et al. [Amicus]—Brief for Amici Curiae The Vaccine Injured Petitioner's Bar Association, et al. Mail Service—02/22/11. Filed: 02/22/11 REV (03/09/11 by C_C) 2009-5052
64	Secretary of Health and Human Services [Appellee]—Supplemental En Banc Reply Brief of Respondent-Appellee Secretary of Health and Human Services. Mail Service—03/21/11. Filed: 03/21/11. REV (04/08/11 by C_C) 2009-5052
65	Appellant [Melissa Cloer, M.D.]—Petitioner-Appellant's Unopposed Request for Oral Argument. Mail Service—03/24/11. Filed: 03/24/11. On consent. Action on Motion (66) Granted by Merits Panel. Filed: 04/13/11. EOD (03/25/11 by KSH) REV (04/13/11 by KSH) 2009-5052
67	NOTICE OF CALENDARING SENT TO PARTIES: Panel 1105N on May 10, 2011, at 10:00 a.m., in Courtroom 201 Court Service—04/13/11. Filed: 04/13/11. REV (04/13/11 by KSH) 2009-5052

* * * * *

DOCKET NUMBER	PROCEEDINGS
70	Submitted after ORAL ARGUMENT by Robert Fishman and Anisha S. Dasgupta. Panel: En Banc and Entered: 05/10/2011. (EOD 05/10/2011 by KSH) 2009-5052
71	Appellee's (Secretary of Health and Human Services) citation of supplemental authority pursuant to Fed. R. App. P. 28(j) (sent to en banc court). Mail Service—05/18/11. Received: 05/18/11. REV (05/19/11 by LB) 2009-5052
72	Appellant Cloer's response to appellee's 5/18/11 citation of supplemental authority (sent to court). Mail Service—05/20/11. Received: 05/23/11. REV (05/23/11 by LB) 2009-5052

DOCKET NUMBER	PROCEEDINGS
74	Appellant [Melissa Cloer, M.D.]—Application for Award of Appellate Attorneys' Fees and Costs [NPF] Mail Service—09/02/11. Filed: 09/06/11. Reply 1 (79) Filed: 10/11/11 Reply 2 (83) Filed: 11/17/11 Action on Motion (86): IT IS ORDERED THAT: Dr. Cloer's application for reasonable attorneys' fees and costs be remanded to the Court of Federal Claims, which is directed to make a determination consistent with this order by Court—En Banc. Filed: 04/11/12. EOD (09/06/11 by LB) REV (04/11/12 by LB) 2009-5052
75	Supplement to Petitioner's Application for Award for Appellate Attorneys' fees and Costs Mail Service—09/09/11. Filed: 09/12/11. REV (09/12/11 by LB) 2009-5052
76	Letter inviting response from appellee to appellant's application for attorneys' fees and costs Court Service—09/14/11. Mailed: 09/14/11 REV (09/14/11 by LB) 2009-5052

DOCKET NUMBER	PROCEEDINGS
77	Appellee [Secretary of Health and Human Services]—Unopposed Motion of Respondent for a 14-Day Extension of Time to File a Response to Petitioner's Application for Appellate Attorneys' Fees Mail Service—09/20/11. Filed: 09/20/11. Action on Motion (78): The Motion is granted. Appellee may file its response by October 11, 2011 by Merits Panel. Filed: 09/22/11. EOD (09/22/11 by LB) REV (09/22/11 by LB) 2009-5052
80	Letter to Mari C. Bush, counsel for appellant, requesting a reply to appellee's opposition to appellant's application for attorneys' fees. Reply not to exceed 25 pages and is due by November 17, 2011. Court Service—10/19/11. Mailed: 10/19/11 REV (10/19/11 by LB) 2009-5052
81	Letter, rec'd 10/24/2011, from Mari Bush, princ. attorney for appellant, requesting withdrawal of her motion for leave to file reply and for video link hearing and reply brief Mail Service—10/21/11. Received: 10/24/11. REV (10/24/11 by LB) 2009-5052

DOCKET NUMBER	PROCEEDINGS
82	Notice from the Clerk of the Supreme Court of the United States of an extension of time, to and including January 2, 2011, to file a petition for a writ of certiorari No Service Required. Received: 10/25/11. REV (10/25/11 by LB) 2009-5052
84	Notice from Clerk of Supreme Court of United States indicating that petition for writ of certiorari was filed on December 29, 2011 and placed on docket as No. 11-832, Melissa Cloer v. Kathleen Sebelius, Secretary of Health and Human Services No Service Required. Received: 01/03/12. REV (01/04/12 by LB) 2009-5052
85	Petition for Writ of Certiorari filed 12/29/11, Supreme Court #: 11-832. Cert. Denied on 04/16/12. REV (04/19/12 by LB) 2009-5052
87	Precedential Order. Opinion for Court filed by Reyna, in which Newman, Linn, Dyk, Moore, O'Malley, and Wallach join. Dissenting opinion filed by Bryson, in which Rader, Lourie, Clevenger, Gajarsa and Prost join. Court Service—04/11/12. Filed: 04/11/12. REV (04/11/12 by LB) 2009-5052 [See entry 86]

DOCKET NUMBER	PROCEEDINGS
88	Notice from the Clerk of the Supreme Court of the United States that the motion of National Vaccine Information Center, et al. for leave to file a brief as amici curiae out of time is granted. The petition for a writ of certiorari is denied. No Service Required. Received: 04/16/12. REV (04/19/12 by LB) 2009-5052
89	Notice from the Clerk of the Supreme Court of the United States of an extension of time to and including August 9, 2012 to file a petition for a writ of certiorari. No Service Required. Received: 6/27/12. REV (07/09/12 by LB) 2009-5052
90	Notice from the Clerk of the Supreme Court of the United States of an extension of time to and including August 23, 2012 to file a petition for writ of certiorari No Service Required. Received: 07/27/12. REV (08/01/12 by LB) 2009-5052

DOCKET NUMBER	PROCEEDINGS
91	Notice from Clerk of Supreme Court of United States indicating that a petition for a writ of certiorari was filed on August 22, 2012 and placed on the docket as No. 12-236, Kathleen Sebelius, Secretary of Health and Human Services v. Melissa Cloer No Service Required. Received: 08/22/12. REV (08/24/12 by LB) 2009-5052
92	Petition for Writ of Certiorari filed 08/22/12. Supreme Court #: 12-236. Cert. Granted on 11/20/12. REV (11/26/12 by LB) 2009-5052
93	Notice from the Clerk of the Supreme Court of the United States that the petition for a writ of certiorari was granted on 11/20/12 No Service Required. Received: 11/20/12. REV (11/26/12 by LB) 2009-5052

UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTER

No. 1:05-vv-01002-LB

MELISSA CLOER, M.D., PETITIONER

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT

Filed: Sept. 16, 2005

DOCKET ENTRIES

DATE	DOCKET NUMBER	PROCEEDINGS
9/16/05	1	PETITION against SECRETARY OF HEALTH AND HUMAN SERVICES [Filed with Exhibits 1-19], (Filing fee $250, Receipt number 063582), filed by MELISSA CLOER, MD. Respondents Report Due by 12/15/2005. (tjk,) (Entered: 09/23/2005)

DATE	DOCKET NUMBER	PROCEEDINGS
9/16/05	2	NOTICE of Assignment to Chief Special Master Gary Golkiewicz. (tjk,) (Entered: 09/23/2005)
10/3/05	3	ORDER The parties shall contact the undersigned's staff attorney by 10/14/05 in order to schedule the initial status conference call. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 10/04/2005)
10/3/05	4	NOTICE of Appearance by Lynn Elizabeth Ricciardella for SECRETARY OF HEALTH AND HUMAN SERVICES. Service: 10/03/05. (tjk,) (Entered: 10/05/2005)

DATE	DOCKET NUMBER	PROCEEDINGS
10/28/05		Minute Entry for proceedings held before Chief Special Master Gary J. Golkiewicz: Status Conference held on October 27, 2005. A Rule 4(b) status conference call was held in which preliminary issues regarding the court's jurisdiction were discussed. Present for petitioner was Ms. Mari Bush, Esq. and Mr. Bob Moxley, Esq. Present for respondent was Ms. Lynn Ricciardella, Esq. (mm1,) (Entered: 10/28/2005)
10/28/05	5	ORDER Petitioner shall file a Status Report due by 11/28/05. Respondent's request for a stay on the filing of the Rule 4(c) Report is granted. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 11/03/2005)
11/[illegible]/05	6	SCHEDULING ORDER: Respondent shall file his Motion to Dismiss due by 12/02/05. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 11/07/2005)

DATE	DOCKET NUMBER	PROCEEDINGS
12/1/05	7	MOTION to Dismiss filed by SECRETARY OF HEALTH AND HUMAN SERVICES. Service: 12/01/05. Response due by 12/19/2005, (tjk,) (Entered: 12/06/2005)
1/3/06	8	ORDER re 7 MOTION to Dismiss pursuant to Rule 12(b)(1) filed by SECRETARY OF HEALTH AND HUMAN SERVICES, Response due by 1/17/2006. Signed by Special Master Gary J. Golkiewicz. (mb2,) (Entered: 01/04/2006)
1/18/06	9	SCHEDULING ORDER: Petitioner shall file her response to 7 Respondent's Motion to Dismiss by 2/16/06. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 01/20/2006)
2/16/06	10	RESPONSE to 7 MOTION to Dismiss, filed by MELISSA CLOER, MD. Service: 2/15/06. Reply due by 2/27/2006. (tjk,) (Entered: 02/21/2006)

DATE	DOCKET NUMBER	PROCEEDINGS
2/16/06	11	NOTICE OF FILING Exhibit #18—Affidavit and curriculum vitae of Dr. Michael Meyer and Exhibit #19—Affidavit and curriculum vitae of Dr. Lenworth Johnson by MELISSA CLOER, MD. Service: 2/15/06. (tjk,) (Entered: 12/22/2006)
2/17/06	12	MOTION for Hearing on Motion to Dismiss, filed by MELISSA CLOER, MD. Service: 2/16/06. Response due by 3/6/2006. (tjk,) (Entered: 02/22/2006)
2/17/06	13	AMENDED BRIEF in Opposition to Respondent's Motion to Dismiss, filed by MELISSA CLOER, MD. Service: 2/16/06. (tjk,) (Entered: 02/22/2006)

DATE	DOCKET NUMBER	PROCEEDINGS
2/27/06	14	SCHEDULING ORDER: Respondent shall file a reply to Petitioner's Opposition to Respondent's Motion to Dismiss and Petitioner's Amended Brief in Opposition to Respondent's Motion to Dismiss due by 3/13/06. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 03/07/2006)
3/13/06	15	REPLY to Response to Motion re 7 MOTION to Dismiss, filed by SECRETARY OF HEALTH AND HUMAN SERVICES. Service: 3/13/06. (tjk,) (Entered: 03/15/2006)
3/16/06	16	SCHEDULING ORDER: Petitioner shall file a response to respondent's argument regarding the applicability of section 16(b) to the facts of this case by no later than 3/30/2006. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 03/21/2006)

DATE	DOCKET NUMBER	PROCEEDINGS
3/28/06	17	ORDER: for petitioner to file response Notice of Compliance due by 4/7/2006. Signed by Special Master Gary J. Golkiewicz. (mij,) (Entered: 03/31/2006)
		* * * * *
4/6/06	18	NOTICE OF FILING Exhibit #20—Budgetary and Statistical Information regarding the NVICP by MELISSA CLOER, MD. Service: 4/06/06. (tjk,) (Entered: 04/12/2006)
4/7/06	19	RESPONSE to respondent's argument regarding the applicability of section 16(b), filed by MELISSA CLOER, MD. Service: 4/06/06. (tjk,) (Entered: 04/13/2006)
4/21/06	20	SCHEDULING ORDER: Respondent's Response due by 5/12/2006. Signed by Special Master Gary J. Golkiewicz. (mij,) (Entered: 04/25/2006)

DATE	DOCKET NUMBER	PROCEEDINGS
4/25/06	21	NOTICE OF FILING Exhibit #21 —Budgetary and Statistical Information by MELISSA CLOER, MD. Service: 4/24/06. (tjk,) (Entered: 04/27/2006)
4/25/06	21	MOTION for inclusion in materials considered as part of pending motion to dismiss, filed by MELISSA CLOER, MD. Service: 4/24/06. Response due by 5/11/2006. (tjk,) Modified on 4/27/2006 (tjk,). (Entered: 04/27/2006)
5/11/06	22	STATUS CONFERENCE ORDER: Status Conference set for 5/15/2006 11:30 AM before Chief Special Master Gary J. Golkiewicz. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 05/12/2006

DATE	DOCKET NUMBER	PROCEEDINGS
5/16/06		Minute Entry for proceedings held before Chief Special Master Gary J. Golkiewicz: Status Conference held on May 15, 2006. A telephonic status conference call was held to discuss respondent's response to petitioner's brief regarding section 16(b) of the Vaccine Act. Present for petitioner was Ms. Mari Bush, Esq. and Mr. Bill Moxley, Esq. Present for respondent was Ms. Lynn Ricciardella, Esq. and Ms. Gabrielle Fielding, Esq. (mm1,) (Entered: 05/16/2006)
5/30/06	23	STATUS REPORT, filed by MELISSA CLOER, MD. Service: 5/25/2006. (mij,) (Entered: 06/05/2006)
8/10/06	24	STATUS CONFERENCE ORDER: Status Conference set for 9/21/2006 03:00 PM before Chief Special Master Gary J. Golkiewicz. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 08/11/2006)

DATE	DOCKET NUMBER	PROCEEDINGS
9/22/06	25	STATUS REPORT ORDER Petitioner shall file a Status Report due by 10/23/2006. If petitioner does not indicate how she intends to proceed in the status report, in the alternative, the parties shall confer and contact the court by 10/30/06, with three dates of availability to schedule a status conference. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 09/26/2006)
9/27/06		Minute Entry for proceedings held before Chief Special Master Gary J. Golkiewicz: A status conference was held on September 21, 2006 to discuss the next steps in this case. Present for petitioner was Ms. Bush and Mr. Moxley. Present for respondent was Ms. Ricciardella. (mm1,) (Entered: 09/27/2006)
10/24/06	26	STATUS REPORT, filed by MELISSA CLOER, MD. Service: 10/23/06. (tjk,) (Entered: 10/25/06)

DATE	DOCKET NUMBER	PROCEEDINGS
11/1/06	27	SCHEDULING ORDER: Petitioner shall file an affidavit from Dr. Meyer and supporting legal authority by no later than 11/30/06. Alternatively, petitioner shall confer with respondent and contact the undersigned's staff attorney by no later than 12/08/06, with three dates that the parties are available in which to schedule a status conference call. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 11/05/2006)
12/6/06	28	SCHEDULING ORDER: Petitioner's request for an enlargement of time is granted. Petitioner shall file an Affidavit from Dr. Meyer and supporting legal authority due by 12/29/2006. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 12/07/2006)
1/5/07	29	MOTION to redesignate exhibits, filed by MELISSA CLOER, MD. Service: 1/04/07. Response due by 1/22/2007. (tjk,) (Entered: 01/11/2007)

DATE	DOCKET NUMBER	PROCEEDINGS
1/5/07	30	PETITIONER'S SUPPLEMENTAL AUTHORITY by MELISSA CLOER, MD. Service: 1/04/07. (tjk,) (Entered: 01/11/2007)
1/5/07	31	NOTICE OF FILING: Exhibit 23—AFFIDAVIT and Exhibit #24—U.S. Dept of HHS/HRSA Web site re NVICP by MELISSA CLOER, MD. Service: 1/04/07. (tjk,) (Entered: 01/11/2007)
2/1/07	32	SCHEDULING ORDER: Respondent shall file a Response 31 due by 2/09/07. Petitioner shall file any reply no later than 30 days from the filing of the Response. Within 14 days of Petitioner's reply, petitioner's counsel shall contact respondent's counsel to agree on three proposed dates and times for a status conference. Petitioner shall contact the undersigned's office with this information. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 02/04/2007)

DATE	DOCKET NUMBER	PROCEEDINGS
2/2/07		Minute Entry for proceedings held before Chief Special Master Gary J. Golkiewicz: Status Conference held on 1/26/2007 to discuss petitioner's Supplemental Affidavit of Michael A. Meyer (Exhibit 23) and Petitioner's Supplemental Authority filed on January 5, 2007. Respondent to file a response to the aforementioned filings by no later than Friday, February 9, 2007. Present for petitioner was Ms. Bush and Mr. Moxley. Present for respondent was Ms. Ricciardella. (jam,) (Entered: 02/02/2007)
2/9/07	33	RESPONSE to 30 Notice of Filing, filed by SECRETARY OF HEALTH AND HUMAN SERVICES. Service: 2/09/07. (tjk,) (Entered: 02/14/2007)
3/9/07	34	RESPONSE to 15 Reply to Response to Motion, filed by MELISSA CLOER, MD. Service: 3/08/07. (tjk,) (Entered: 03/16/2007)

DATE	DOCKET NUMBER	PROCEEDINGS
3/15/07		Minute Entry for proceedings held before Chief Special Master Gary J. Golkiewicz: Telephonic Status Conference held on 3/14/2007 to discuss Respondent's Oral Objection to Petitioner's request for an additional 30 days to file another affidavit from Dr. Mayer and the issues presented in this case in light of the recent Markovitch decision from the Federal Circuit. (jam,) (Entered: 03/15/2007)

DATE	DOCKET NUMBER	PROCEEDINGS
3/15/07	35	SCHEDULING ORDER: Pursuant to the status conference held on 3/14/07: Petitioner shall file her Second Affidavit of Dr. Meyer by no later than 4/13/07. Respondent shall file any reply no later than 30 days from the filing of petitioner's Second Supplemental Affidavit. Within 7 days of respondent's reply, petitioner's counsel shall contact respondent to agree upon dates and times for the status conference. Petitioner shall contact the undersigned's office with this information. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 03/18/2007)
4/13/07	36	MOTION for Extension of Time until 4/27/07 to file affidavit of Dr. Meyer, filed by MELISSA CLOER, MD. Service: 4/12/07. Response due by 4/30/2007. (Neal, Alonzo) (Entered: 04/19/2007)

DATE	DOCKET NUMBER	PROCEEDINGS
4/18/07	37	ORDER Notice of Compliance due by 4/30/2007. Signed by Special Master Gary J. Golkiewicz. (Neal, Alonzo) (Entered: 04/23/2007)
4/20/07	38	ORDER granting 36 Motion for Extension of Time Expert Report due by 4/30/2007. This order supersedes the 37 Order filed by the undersigned on 4/18/07. Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 04/24/2007)
5/2/07	39	AFFIDAVIT of Dr. Meyer (Exhibit #25) by MELISSA CLOER, MD. Service: 5/01/07. (tjk,) (Entered: 05/05/2007)
5/4/07	40	[RESPONDENT'S REPLY to PETITIONER'S SECOND SUPPLEMENTAL AFFIDAVIT of Michael A. Meyer, M.D.] RESPONSE to 35 Scheduling Order,,, filed by SECRETARY OF HEALTH AND HUMAN SERVICES. Service: 5/04/07. (tjk,) (Entered: 05/07/2007)

DATE	DOCKET NUMBER	PROCEEDINGS
5/24/07		Minute Entry for proceedings held before Chief Special Master Gary J. Golkiewicz: Telephonic Status Conference held on 5/21/07 to discuss PETITIONER'S SECOND SUPPLEMENTAL AFFIDAVIT of Michael A. Meyer and Respondent's Reply. Present for Petitioner was Ms. Bush and Mr. Moxley. Present for respondent was Ms. Ricciardella. (jam,) (Entered: 5/24/2007)
6/25/07	41	HEARING ORDER: Telephonic Hearing set for 8/30/2007 01:00 PM before Chief Special Master Gary J. Golkiewicz. Signed by Special Master Gary J. Golkiewicz. (tjk,) Entered: 06/27/2007)

DATE	DOCKET NUMBER	PROCEEDINGS
8/31/07		Minute Entry for proceedings held before Chief Special Master Gary J. Golkiewicz: Telephonic Hearing held on 8/30/2007 to take the testimony of Dr. Meyer. Present for petitioner was Ms. Bush and Mr. Moxley. Present for respondent was Ms. Ricciardella. (jam,) (Entered: 08/31/2007)
9/14/07	42	TRANSCRIPT of Proceedings (pages 1-58) held on August 30, 2007 before Chief Special Master Gary J. Golkiewicz. (dw1) (Entered: 09/18/2007)
9/19/07	43	ORDER re Petitioner shall file a Joint Status Report with the court within 7 days of the filing of the transcript for the 8/31/07 hearing. The report shall indicate whether the parties wish to file post hearing briefs and, if so, shall suggest an agreed upon procedure and time frame for doing so. Signed by Special Master Gary J. Golkiewicz. (sm) (Entered: 09/19/2007)

DATE	DOCKET NUMBER	PROCEEDINGS
9/24/07	44	STATUS REPORT ORDER On 9/20/07, the parties made a joint oral motion for a continuance of time until 10/02/07 to file a joint status report regarding post hearing briefs. That motion is GRANTED. The parties shall file the Joint Status Report due by 10/2/2007 Signed by Special Master Gary J. Golkiewicz. (tjk,) (Entered: 09/28/2007)
10/2/07	45	STATUS REPORT, filed by MELISSA CLOER, MD. Service: 10/1/07. (Neal, Alonzo) (Entered: 10/04/2007)
10/5/07	46	SCHEDULING ORDER: Petitioner's Post Hearing Brief due by 11/1/2007. Respondent's post hearing reply brief due by 11/15/2007. Signed by Special Master Gary J. Golkiewicz. (Neal, Alonzo) (Entered: 10/10/2007)

DATE	DOCKET NUMBER	PROCEEDINGS
11/1/07	47	AFFIDAVIT of Dr. Melissa Closer (September 2007 Ex. 26) by MELISSA CLOER, MD. Service: 10/31/07. (Neal, Alonzo) (Entered: 11/05/2007)
11/1/07	48	POST HEARING BRIEF by MELISSA CLOER, MD. Service: 10/31/07. (Neal, Alonzo) (Entered: 11/05/2007)
11/9/07	49	REPLY to 48 Post Hearing Brief, filed by SECRETARY OF HEALTH AND HUMAN SERVICES. Service: 11/09/07. (tjk,) (Entered: 11/13/2007)
5/15/08	50	DECISION Signed by Chief Special Master Gary J. Golkiewicz. Fedex on 5/15/08, tracking number 865183147514. (Neal, Alonzo) (Entered: 05/22/2008)

* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
6/16/08	53	MOTION for Review of 50 DECISION of Special Master *Golkiewicz*, filed by MELISSA CLOER, MD. Response to Motion for Review due by 7/16/2008. (Attachments: #1 Memorandum of Objections) (Bush, Mari) Modified on 6/18/2008 to correct response due date. (dls). (Entered: 06/16/2008)
6/16/08	54	NOTICE of Assignment to Judge Lawrence J. Block. (dls) (Entered: 06/18/2008)
6/16/08		Case assigned to Judge Lawrence J. Block. (dls) (Entered: 06/18/2008)
6/16/08		Reset Deadline: Response to Motion for Review due by 7/16/2008. (dls) (Entered: 06/18/2008)
6/20/08	55	MOTION for Leave to Exceed Page Limit of Memorandum of Objections by 15 pages, filed by MELISSA CLOER, MD. Response due by 7/7/2008. (Bush, Mari) (Entered: 06/20/2008)

DATE	DOCKET NUMBER	PROCEEDINGS
6/23/08		ORDER—The 55 motion for leave to exceed the page limitation is GRANTED. Accordingly, the Court recognizes petitioner's 53 motion to seek review, as already filed on 6/16/08. Signed by Judge Lawrence J. Block. (smm) (Entered: 06/23/2008)
7/16/08	56	RESPONSE to 53 MOTION for Review of 50 DECISION of Special Master *Golkiewicz* MOTION for Review of 50 DECISION of Special Master *Golkiewicz*, filed by SECRETARY OF HEALTH AND HUMAN SERVICES. (Ricciardella, Lynn) (Entered: 07/16/2008)
7/25/08	57	MOTION for Leave to File Reply Memorandum, filed by MELISSA CLOER, MD. Response due by 8/11/2008. (Bush, Mari) (Entered: 07/25/2008)
7/25/08	58	MOTION Oral Argument *Via Video Link*, filed by MELISSA CLOER, MD. Response due by 8/11/2008. (Bush, Mari) (Entered: 07/25/2008)

DATE	DOCKET NUMBER	PROCEEDINGS
8/7/08		ORDER—The 57 motion for leave to file is hereby DENIED. Additionally, the 58 motion for oral argument via video link is hereby DENIED. Signed by Judge Lawrence J. Block. (smm) (Entered: 08/07/2008)
11/25/08	- 59	SEALED OPINION—Filed this date. 53 motion for review is DENIED. The Clerk is directed to dismiss the case. The PARTIES SHALL FILE by Tuesday, 12/9/08, any PROPOSED REDACTIONS WITHIN the the SEALED OPINION. Signed by Judge Lawrence J. Block. (smm) (Entered: 11/25/2008)
11/26/08	60	JUDGMENT entered, pursuant to Appendix B, Vaccine Rule 30, dismissing the petition with prejudice. (dls) (Entered: 11/26/2008)
12/10/08	61	PUBLISHED OPINION. Filed this date UNSEALED. Signed by Judge Lawrence J. Block. (smm) (Entered: 12/10/2008)

DATE	DOCKET NUMBER	PROCEEDINGS
3/9/09	62	CAFC Notice of Review, with CAFC case no. 2009-5052. (hwl,) (Entered: 03/09/2009)
8/5/11	63	Decision of the Court of Appeals for the Federal Circuit. The mandate will issue in due course, approximately by 9/29/2011. (hwl) (Entered: 08/08/2011)
9/26/11	64	MANDATE of CAFC affirming 59 Order directing the Clerk to dismiss the case and enter judgment. (hwl) (Entered: 09/27/2011)
9/5/12	65	ORDER REASSIGNING CASE to Special Master Vowell. Signed by Chief Special Master Patricia E. Campbell-Smith. (ds8) Copy to parties. (Entered: 09/05/2012)
9/5/12		Case Reassigned to Special Master Denise Kathryn Vowell pursuant to Vaccine Rule 3(d). Special Master Gary J. Golkiewicz no longer assigned to the case. (tjk) (Entered: 09/05/2012)

UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 05-VV-01002-LB

MELISSA CLOER, M.D., PETITIONER

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT

[Dated: Sept. 12, 2005]

Exhibit 1

AFFIDAVIT OF MARI BUSH

---

1. My name is Mari C. Bush. I am a partner in the firm of Kaye and Bush, LLC, 2300 15th Street, Suite 200, Denver, CO 80202. I am admitted to practice before the United States Court of Federal Claims.

2. In this action, *Melissa Cloer v. Department of HHS*, Mr. Robert Moxley of Gage and Moxley in Cheyenne, Wyoming is assisting as co-counsel. Mr. Moxley is admitted to practice before the United States Court of Federal Claims.

3. I have made every attempt, directly and through my staff, to obtain all pertinent and required medical records and other documentation for the Petition for Vaccine Compensation filed on behalf of Dr. Melissa Cloer. As Dr. Cloer is an adult, many of her childhood records are not available.
4. The efforts of my office are documented as part of the exhibits submitted with this Petition.
5. Upon information and belief, Dr. Cloer meets all jurisdictional requirements for filing a Vaccine Claim.
6. Upon information and belief, Dr. Cloer has a good faith claim for compensation for injuries arising from her Hep-B vaccinations.
7. This affidavit is signed voluntarily, under penalty of perjury.

FURTHER AFFIANT SAYETH NOT:

/s/ [MARI C. BUSH] [Sept. 12, 2005]
MARI C. BUSH Date

UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 05-VV-01002-LB

MELISSA CLOER, M.D., PETITIONER

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT

[Dated: Aug. 25, 2005]

Exhibit 2

AFFIDAVIT OF MELISSA L. CLOER, MD

Comes now the Petitioner, Melissa L. Cloer, MD, and hereby states under penalty of perjury.

1. I was born on January 22, 1968 at Midland Memorial Hospital in Midland, Texas.

2. My early childhood medical care was provided by Dr. John W. Lister. His office was at 1908 W. Wall, Midland, Texas. I have tried to contact Dr. Lister and obtain his records of my care. Dr. Lister cannot be located, nor can his records, despite all reasonable efforts. I assume he must be deceased.

3. I received routine medical care from Dr. Ronal Legako of Canyon Park Family Physicians in Edmond, Oklahoma.

4. During my childhood and teenage years, I had no significant illnesses or injuries. I recall receiving some medical care during my childhood at Mercy Health Center, 4300 West Memorial Road, Oklahoma City, Oklahoma (for e.g., an asthma attack; fall off of bike). I also received care from Dr. Paul Silverstein, a plastic surgeon who repaired my lip after a dog bite in the late 1970s. Dr. Silverstein's address is 3301 NW 63rd Street, Oklahoma City, Oklahoma.

5. In approximately 1991 or 1992, I saw a family practitioner once in Ponca City, Oklahoma, possibly at the White Eagle Indian Health Center.

6. In the 1994-1996 time period, I received ob/gyn care from Dr. Jennifer Nelson at 11200 North Portland Avenue, Oklahoma City, OK. During this time period I was known as Melissa Garcia or Melissa Cloer-Garcia.

7. In addition, I have also been treated by Dr. Misty Hseih, a Family Practice physician at Citizen Potawatomi Nation: Clinic and Health Services in Shawnee, Oklahoma.

8. While a student at the University of Missouri in Columbia, I received care and treatment at the University's Student Health Center. Some of those records would reflect my then-married

name, Melissa Myers. Only a small part of my care was provided at the student health center. The other part (majority) was through the University Physicians (University of Missouri-Columbia) health plan (includes Dr. Meyer, Dr. Colapinto, Dr. Pereira, Dr. Horowitz, Dr. Johnson).

9. I received 3 Hep-B immunizations in 1996-1997 through the Student Health Center. Specifically, I received the Hep-B immunizations reflected on my Adult Vaccination Record, all manufactured by Smith Kline Beecham: (a) on 9/3/96, I received Smith Kline Beecham #2123A2; (b) on November 11, 1996, I received another Smith Kline Beecham #2004A21; and (c) on April 3, 1997, I received another Hep-B #2235H2 or #2235A2.

10. Apart from the injuries associated with my MS, I have enjoyed good health throughout my life.

11. Dr. Kevin Wood is my treating neurologist. He has been treating me since 2003.

12. In late 2003, I was diagnosed with multiple sclerosis. While I had experienced some isolated symptoms prior to that time, it wasn't until November 2003 that probable multiple sclerosis was diagnosed.

13. For instance, in 1997 I had an electric shock sensation in my spine and numbness in my left forearms and hand. My family practice physician,

Dr. Susan Pereira, prescribed Motrin and the symptoms resolved over a short period of time. An MRI done on May 12, 1998 included differential diagnoses of MS, Lymes Disease, ADEM or other demyelinating processes. Dr. Meyer, the neurologist, described my problem as a "probable early inactive non-progressive" condition.

14. In 1999, I was also evaluated by Dr. Colapinto, a neurosurgeon, and Dr. Meyer, a neurologist. (Ex. 12, pp. 36-7, 41-2) My symptoms would improve, at times, making a definitive diagnosis difficult.

15. Prior to beginning to treat with Dr. Kevin Wood (see below) my health care providers always reassured me about my isolated neurological symptoms. I was reassured that the symptoms were isolated and I was an overreacting medical student. As my symptoms came and went, I believed and hoped that I was not suffering from any major neurological condition.

16. Blurred vision problems prompted me to consult Dr. Johnson at the Mason Eye Institute at the University of Missouri in August 2002. Given my history, Dr. Johnson, the neuro-opthalmologist, found my symptoms consistent with "retrobulbar neuritis" and that the "possibility of demyelinating disease does exist."

17. My first appointment with Dr. Kevin Wood, treating neurologist, was on November 26, 2003. Based on history and examination, Dr. Wood's impression was that I was "likely" suffering MS. Treatment consisted of various medications. An MRI of the brain was also ordered. As of November 26, 2003, Dr. Wood authored a "To Whom it May Concern" letter on my behalf indicating that I have a "provisional diagnosis of multiple sclerosis," and the diagnosis was confirmed with the MRI results shortly thereafter.

18. When I returned to Dr. Wood on December 22, 2003, my MRI results were available, showing " . . . multiple deep white matter lesions strongly suggestive of MS."

19. Dr. Kevin Wood continues to treat me. My treatment included injections of Betaseron, Prednisone, Provigil (for fatigue), Naltrexone and Zanaflex, but I had to discontinue the Betaseron after an injection site necrosis, a contraindication to continued use of interferons. I have undergone occasional steroid tapers, but am not currently taking steroids on an ongoing basis. I no longer take the Provigil or Zanaflex as they were ineffective and actually caused more side effects. I continue with the naltrexone as anecdotal evidence exists for MS and other diseases and I have had subjective improvement with it. Currently, my main treatment is self-treatment with "alternative" means such as

heavy metal chelation for the thimerosal contained in the vaccines, as well as various herbs and vitamins.

20. I had to withdraw from a fellowship in Infectious Diseases due to the disabling effects of my multiple sclerosis.

21. I applied for Social Security Disability. As part of the application process, I was examined by Dr. James P. Metcalfe on June 17, 2004. Based upon his evaluation, Dr. Metcalfe formulated the following clinical impressions: multiple sclerosis; weakness of left upper and left lower extremities secondary to MS; chronic fatigue secondary to MS; spastic gait secondary to MS; and peripheral neuropathy.

    A "Notice of Award" for Social Security Disability benefits was sent to me, finding I became disabled for Social Security purposes as of November 23, 2003.

22. In late 2004, I became aware of an editorial and a prospective study in the September 2004 issue of *Neurology*. The prospective study was entitled "Recombinant Hepatitis B Vaccine and the Risk of Multiple Sclerosis." The authors concluded that these findings are consistent with the hypothesis that immunization with the recombinant Hepatitis B vaccine is associated with an increased risk of MS, and challenge the idea

that the relation between hepatitis B vaccination and risk of MS is well understood.

23. The prospective study described in the September 2004 *Neurology* used a data base that was much better than the data relied upon in earlier studies that showed no correlation; this prospective study had superior methodology compared to earlier cited studies on this topic.

24. It wasn't until I read these articles that I became aware of the association between the Hep-B immunization and the development of MS. After I read these articles, I carefully reviewed my immunization history and the development of my neurological symptoms. I realized there was a strong temporal association between the immunizations and the onset of individual symptoms that were later diagnosed in November 2003 as MS.

25. Within the past year, I contacted Smith Kline Beecham and spoke to the individual who handles vaccine questions for physicians. I provided her with information (such as lot number) regarding the Hep-B I received in 1996 and 1997. She indicated that all three immunizations I received contained 50 micrograms of thimerosol. She would not put this information in writing for me, though, indicating that it was standard for doctors to rely upon information provided over the phone.

26. No prior civil action has been filed by me or any individual or entity on my behalf alleging injuries as a result of vaccine-related problems. In addition, no compensation in the form of an award or settlement has been made to me for vaccine-related injuries.

27. I have incurred in excess of $1,000.00 in unreimbursed, out-of-pocket expenses in connection with my vaccine injuries. For example, I had to have my amalgam fillings taken out so that I could chelate for thimerosal poisoning, and I had to pay monthly health insurance premiums out of pocket while having zero income, until I could no longer afford it. It should also be noted that I am a borderline nursing home candidate now, save for the fact that my parents are nearby to help with shopping, cooking, cleaning, the basics. There is no way I could survive on my own.

28. I have had to give up my medical training and employment, suffer from extreme fatigue and require medication and assistance. My MS condition has persisted for more than 6 months after the administration of the Hep-B vaccine.

FURTHER AFFIANT SAYETH NOT:

Date: [Aug. 25, 2005] Respectfully submitted,

/s/ [MELISSA L. CLOER, MD]
MELISSA L. CLOER, MD

UNITED STATES COURT OF FEDERAL CLAIMS
FOR THE OFFICE OF SPECIAL MASTERS

No. 05-VV-01002-LB

MELISSA CLOER, M.D., PETITIONER

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT

[Dated: Feb. 12, 2006]

Exhibit 20

AFFIDAVIT OF MICHAEL A. MEYER, M.D.

---

1. My name Is Michael A. Meyer, M.D. I am a Professor of Clinical Neurology and Nuclear Medicine, at the State UNiversity of New York School of Medicine in Buffalo. I am affiliated with the Jacobs Neurological Institute in Buffalo, New York. My professional address is 100 High Street in Buffalo, New York.

2. This affidavit is based upon my experience, training and education. This affidavit is based upon a reasonable degree of probability in the field of Neurology.

3. I have recently had an opportunity to review the records of Melissa Cloer when she was a patient at University Hospital and Clinics in Columbia, Missouri. My affidavit testimony is based upon my personal knowledge, information and belief as well as my custom and practice.

4. By way of background, I received my BA degree from Columbia University in New York, New York and my M.D. degree from Albany Medical College in Albany, New York.

5. My internship and residency was at the Mayo Clinic in Rochester, Minnesota. I completed fellowships in Nuclear Medicine and PET at both the University of Pennsylvania and the University of Michigan.

6. I am board certified in Neurology, Nuclear Medicine and Nuclear Cardiology.

7. My clinical interests include Multiple Sclerosis, memory disorders, Nuclear Medicine and Neuro-oncology. My research interests include Multiple Sclerosis and Neuro-oncology.

8. Previously, I provided medical care in 1998 to Dr. Melissa Cloer. At the time I evaluated her, she was a medical student at the University of Missouri and I was affiliated with University Hospital & Clinics at the University of Missouri (Columbia). Her name was Melissa L. Myers at that time.

9. I have had an opportunity to review my medical charting of Dr. Cloer from 4-28-98 and 5-15-98, as well as all of her other medical records pertaining to neurological and other medical issues.

10. At the time I evaluated Dr. Cloer in 1998, she had not yet been formally diagnosed with the clinical syndrome complex of multiple sclerosis (MS).

11. There had been no manifestation for the onset of clinically definite multiple sclerosis during the time period I evaluated Dr. Cloer.

12. During the time that I evaluated Dr. Cloer, she had the manifestations of onset of what can be termed "singular sclerosis"; from the available clinical and radiographic evidence that was available at that time, she had what appeared to be early Inactive non-progressive CNS demyelinating disease, which as we discussed at that time, could possibly remain a single, isolated event with no further sequlae, with her MRI showing a cluster of punctuate FLAIR hyperintensitites seen in one subcortical location at the posterior aspect lateral to the left lateral ventricle.

13. The diagnosis or manifestation of onset of Multiple Sclerosis requires multiple events over time and space, confirmed by clinical history, neurologic exam, and radiographic examination. Similarly, the diagnosis or manifestation of onset

of Multiple Sclerosis requires multiple lesions in multiple areas of the central nervous system. When a case in which a "singular sclerosis" event has occurred, such as with Dr. Cloer, many years may elapse before there is enough evidence to meet the requirements of multiple events over time and space plus multiple lesions over time and space to satisfy the definition of multiple sclerosis and therefore the manifestation of the clinical syndrome complex termed multiple sclerosis.

14. At the time I evaluated Dr. Cloer, her clinical picture was such that her condition may have remained stable or non-progressive.

15. In terms of the MRI I obtained of Dr. Cloer's brain on May 12, 1998, two punctate lesions clustered together were observed in the posterior aspect of the left periventricular subcortical region. Lesions in this area on the left side of the brain did not correlate with the complaints of numbness and parasthesias in the left hand (the patient was also concerned if this was in the ulnar distribution of her left arm). Areas of demyelination which could anatomically correspond to this would be more likely to be reflected on the right side of her brain on MRI imaging, but there were none, making the whole scenario much more difficult to define.

16. I have had an opportunity to look at the Nov. 26, 2003 2003 brain MRI of Dr. Cloer, which dis-

played multiple areas of demyelination, many with peripheral enhancement, and in a pattern and distribution typically seen in a patient with multiple sclerosis. This displays dramatically increased demyelinating activity seen radiographically since the time where I first saw her, as well as her clinical history consistent with multiple attacks. At this time, it would be appropriate to consider multiple sclerosis as manifesting itself in 2003.

17 During the time I evaluated Dr. Cloer, a potential association between Hep-B vaccinations and MS was not firmly established in the medical literature or part of general knowledge. In retrospect, it is now realized that there were increasingly more frequent reports in French medical journals in the late 1990s on MS onset or relapse after the extensive immunization program in France against Hep B (Touze E, et. al. Premier episode de demyelinsation du system nerveux central et vaccination contre l'hepatite B: etude cas-temoins pilote. Rev Neurol (Paris) 2000; 156; 242-6). I have a special interest in the relation between viruses and MS, and was not aware of how controversial this issue is regarding the relation between Hep-B vaccinations and MS, until contacted by Dr. Cloer and her counsel in late 2005. Likewise, I was not generally aware of the above cited French medical literature about the potential association between Hep-B

immunizations and MS until contacted by Dr. Cloer and her counsel in late 2005.

18. It is my understanding that Dr. Cloer was later evaluated by Dr. Kevin Wood, a neurologist. I have been provided with his note of November 26, 2003. To the extent the history reflected in Dr. Wood's note indicates that Dr. Cloer was recommended for treatment for MS, but did not take any, that would not necessarily apply to my evaluation of Dr. Cloer.

19. This affidavit testimony is provided voluntarily and it is signed under penalty of perjury.

/s/ [ILLEGIBLE] [2/12/06]

DR. MICHAEL A. MEYER/Signature Date

[IMAGE OMITTED]

Michael A. Meyer, M.D.

Professor of Clinical Neurology and Nuclear Medicine

Board Certifications:	Neurology, Nuclear Medicine, Nuclear Cardiology
Clinical Interests:	Multiple Sclerosis Memory Disorders Nuclear Medicine Neuro-oncology
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UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 05-VV-01002-LB
Chief Special Master Golkiewicz

MELISSA CLOER, M.D., PETITIONER

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT

[Dated: Dec. 15, 2005]

Exhibit 21

AFFIDAVIT OF LENWORTH N. JOHNSON, M.D.

---

1. My name is Lenworth N. Johnson, MD. I am a Neuro-Ophthalmologist and Professor of Ophthalmology and Neurology at the University of Missouri-Columbia, School of Medicine. My professional address is One Hospital Drive, Columbia, MO 65212.

2. A copy of my curriculum vitae is attached hereto and incorporated herein by reference. By way of summary, I am a graduate of Albany Medical College in Albany, New York. My residency was at

the University of California-Irvine as well as the Albany Medical Center. I have completed additional work by way of a Fellowship in neuro-ophthalmology at the Jules Stein Eye Institute at the University of California, Los Angeles.

3. I am board certified in Ophthalmology. I have been published in peer-reviewed medical journals and involved in various research projects.

4. As part of my clinical practice, I did a consultation and evaluation of Melissa (Myers) Cloer, MD while she was a resident in Internal Medicine at the University of Missouri. This took place in August 2002 and the related notes, report and records are attached.

5. I have had an opportunity to review my notes of this consultation and examination and to speak with Dr. Cloer, formerly Dr. Myers.

6. Dr. Cloer, at the time she consulted with me, had a recent episode with central blurred vision of the left eye. Her symptoms were slowly improving as of the time I examined her.

7. Based upon the history and examination that I obtained, she had symptoms consistent with retrobulbar neuritis.

8. As set forth in my report, no probable diagnosis of demyelinating disease was made at that time.

9. As set forth in my report, no specific medical or surgical treatment was offered or indicated at that

time for her visual symptoms. Specifically, my report indicates: "There are no indications for medical or surgical therapy at this time. We will not be scheduling Dr. Myers [now Dr. Cloer] for a specific follow-up appointment at this time. . . . it was explained that should she have worsening symptoms, she should feel free to contact us to make an appointment in order to be evaluated."

10. It is my understanding that Dr. Cloer was later evaluated by Dr. Kevin Wood, a neurologist. I have been provided with his note of November 26, 2003. To the extent the history reflected in Dr. Wood's note indicates that Dr. Cloer was recommended for treatment for MS, but did not take any, that would not apply to my care and treatment of Dr. Cloer.

11. Further, I would disagree with the history set forth in Dr. Wood's note of November 26, 2003 where it indicates that: "In the fall of 2002, she had a right-sided visual field defect. She say [sic] a neuro-ophthalmologist who felt it was retrobulbar neuritis and he again urged her to get treatment, but she decided against it." This is erroneous. She had symptoms in the left eye when I consulted with her. I did not urge any treatment, so Dr. Cloer was not in a position to decide against treatment at that point.

12. This affidavit is based upon my personal knowledge, information and belief, as well as my review of the medical records mentioned. To the extent

any opinions are provided, they are based upon a reasonable degree of probability in the field of neuro-ophthalmology.

13. This affidavit is given voluntarily and is my sworn testimony.

FURTHER AFFIANT SAYETH NOT:

/s/ [ILLEGIBLE] [12/15/05]

LENWORTH N. JOHNSON, MD — Date

(signature)

UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTER

No. 05-VV-01002-LB
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SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT

[Dated: Dec. 15, 2006]

Exhibit 23

SUPPLEMENTAL AFFIDAVIT OF MICHAEL A. MEYER, MD

---

1. My name is Michael A. Meyer MD, University of Buffalo Professor of Clinical Neurology and Nuclear Medicine and had been associated with the Baird Multiple Sclerosis Center at the Jacobs Neurological Institute, 100 High Street, Buffalo NY

2. The affidavit is based upon my experience, training and education. This affidavit is based upon a reasonable degree of certainty in the field of

Neurology. The affidavit is to supplement and further clarify the affidavit I previously submitted. The previous affidavit is incorporated herein by reference as if fully set forth. The affidavit is signed under penalty of perjury.

3. As stated before I have had an opportunity to review the records of Melissa Cloer when she was a patient at the University of Missouri at Columbia Health Science Center. My affidavit is based on personal knowledge, information and belief as well as my custom and practice as well as review of other records provided to me subsequent to care at the Neurology Dept clinic at Univ Missouri. Likewise, my affidavit takes into account my education training and experience. Moreover I have spoken with Dr. Cloer and reviewed updated medical information including diagnostic imaging studies related to here illness

4. By way of background, I received my BA degree from Columbia University in New York NY and my MD degree from Albany Medical College in Albany NY. My residency was at the Mayo Clinic in Rochester MN, and completed fellowships in Nuclear Medicine and PET at the University of Pennsylvania and Univ Michigan. I am board certified in Neurology, Nuclear Medicine and Nuclear Cardiology My clinical interests include Multiple Sclerosis, Stroke and Neuro-Oncology. My research interest also includes Multiple Sclerosis.

5. Previously, I provided medical care to Dr. Melissa Cloer. At the time I evaluated her, she was a medical student at the University of Missouri and I was affiliated with Univ. Hospitals and Clinics at the University of Missouri. Here name at that time was Melissa Myers.

6. At the time I evaluated Dr. Cloer in 1998, she had not yet been formally diagnosed with clinically definite multiple sclerosis (MS)

7. It is my understating that the Court would like me to further address the issue of how Dr. Cloer's earlier symptoms were not, in an of themselves diagnostic of Multiple Sclerosis (MS) in a clinically definite form

8. The accepted diagnosis of MS requires multiple events over time and space with multiple lesions in multiple areas of the central nervous system seen on MRI. Based upon my retrospective review of the medical records sent to me, and personal knowledge of Dr. Cloer medical course, she did not clearly meet formal diagnostic criteria, including MR criteria until a Nov. 26 2003 MRI performed at Southwest Oklahoma MRI revealed multiple lesions with enhancement, which was radically different from her prior MRI evaluation at the University of Missouri. It should also be noted that a University of Missouri neuro-opthalmologist made note of a left eye central blurring to her vision in August 2002.

9. When I evaluated Dr. Cloer in April and May of 1998, she did not meet formal diagnostic criteria for clinically definite MS. Rather the diagnosis would be more typically be termed demyelinating disease with a singular area of region of involvement without multiple lesions being evident at that time. As of 1998, Dr. Cloer experienced symptoms that could have never returned or progressed.

10. When I evaluated Dr. Cloer in 1998, her singular demyelinating change could have remained a clinically isolated event with no sequelae. At the time I evaluated her in 1998, her condition may have remained stable or non-progressive.

11. When I evaluated Dr. Cloer in 1998 I would not have told her she had clinically definite MS

12. By way of further support, Clinical Neurology, 3rd edition, described MS and states:

    " . . . . note that the diagnosis can not be based on any single symptom or sign but only a total clinical picture that indicates involvement of different parts of the central nervous system . . (Investigative studies) may help support the clinical diagnosis and exclude other disorders but do not themselves justify a definitive diagnosis of multiple sclerosis"

13. During the time I evaluated Dr. Cloer, she had the manifestation of onset what may to be termed "singular sclerosis." She only had de-

myelinating disease at the time I evaluated here, and could possibly remain a single isolated event with no further sequelae

14. The May 1998 MRI of the brain did not reveal a lesion that could explain the sensory complaints of numbness and paraesthesias in the left ulnar distribution of her left upper extremity - the only change consisted of two small hyperintensities in the posterior left peri-ventricular region.

15 It is my understanding that the National Vaccine Injury Compensation Program expects that individuals should file a petition for a vaccine related injury within three years "after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury"

16. As a health care professional asked to opine as to wording of "manifestation". It should be noted that Webster Dictionary defines "manifest" as to "make evident or certain by showing or displaying; readily perceived by the senses, especially by sight, easily understood or recognized by the mind"

17. Similarly, the on-line medical definition for manifest is noted as follows: Being the part or aspect of a phenomenon that is directly observable: concretely expressed in behavior, and that "manifestation" is: "Something that manifest or

constitutes on expression of something else: a perceptible, outward or visible expression." (source: OMD, Published at the Dept. of Medical Oncology, University of Newcastle upon Tyne)

18. It is important to note that medical literature has not convincingly disproved a relation between hepatitis vaccination and multiple sclerosis, and that it is well known that central nervous system demyelination and MS like syndromes can result after vaccinations. For example the 2006 case report by Terney and colleagues clearly reveal MS onset only 10 weeks after a May 1999 Hepatitis B vaccination; the time delay of 7 years for this case to appear in the medical literature is also important to note. (Terney D, Beniczky S, Barsi P, Kondakor I, Perenyi J, Faludi B, Szapper M, Vecsei L. Multiple sclerosis after hepatitis B vaccination in a 16-year-old patient. Chin Med J (Engl). 2006 Jan 5; 119(1):77-9)

19. It also important to note that Hernan and colleagues have published data recently in 2004 that finds a link between MS and hepatitis B vaccination (Hernan MA, Jick SS, Olek MJ, Jick H. Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study. Neurology. 2004 Sep 14; 63(5):838-42.). As noted in their paper, the analyses include 163 cases of MS and 1,604 controls. The odds ratio (OR) of MS

for Vaccination within 3 years before the index date compared to no vaccination was 3.1 (95% CI 1.5, 6.3). No increased risk of MS was associated with tetanus and influenza vaccinations. The study concluded that these findings are consistent with the hypothesis that immunization with the recombinant hepatitis B vaccine is associated with an increased risk of MS, and challenge the idea that the relation between hepatitis B vaccination and risk of MS is well understood

20. It is also important to note that there can be a great delay between symptoms and actual diagnosis for MS. This often can be significantly greater than the 3 year period listed by National Vaccine Injury Compensation Program for consideration. In fact, data relating to this has been obtained in relation to the year in which symptoms may have appeared. For Caucasian females later found to have MS, a retrospective review found a mean of 7.68 years plus or minus 5.4 years if their symptoms started in the 1980 to 1984 time period, and that the mean plus one standard deviation was 3.7 years for those with first symptoms in the 1995 to 1999 time period (1.9 years plus or minus 1.8 years as listed in table one of study from: Marrie RA, Cutter G, Tyry T, Hadjimichael O, Campagnolo D, Vollmer T. Changes in the ascertainment of multiple sclerosis. Neurology. 2005 Oct 11;65(7):1066-70). This figure reflects only mean time for a

group of patients, and reflects the long delay which may occur between symptom onset and disease diagnosis. It should also be noted that between the first April 1998 evaluation and the August 2002 visual symptoms, approximately 3.7 years had elapsed.

21. It is clear from the records available to me for review that no formal diagnosis of probable MS was made by a physician until November 26th, 2003

/s/ MICHAEL A. MEYER [2/15/06]
MICHAEL A. MEYER MD Date

[NOTARY PUBLIC STAMP OMITTED]

UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTER

No. 05-VV-01002-LB

MELISSA CLOER, M.D., PETITIONER

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
RESPONDENT

Exhibit 24

HRSA

National Vaccine Injury Compensation Program (VICP)

- Covered Vaccines
- Persons Eligible to File a Claim
- Filing a Claim with the VICP
- Filing Deadlines
- Vaccine Injury Table list of vaccines and specialized injuries covered under the program
- Frequently Asked Questions
- Statistics Reports
- Strategic Plan
- Advisory Commission on Childhood Vaccines (ACCV)
- Contact Information

About VICP

On October 1, 1988, the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) created the National Vaccine Injury Compensation Program (VICP). The VICP was established to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines. The U. S. Court of Federal Claims decides who will be paid. Three Federal government offices have a role in the VICP:

- the U.S. Department of Health and Human Services (HHS);
- the U.S. Department of Justice (DOJ); and
- the U.S. Court of Federal Claims (the Court).

The VICP is located in the HHS, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Vaccine Injury Compensation.

Additional HHS Vaccine Information

- Childhood Immunization Information for Consumers (National Library of Medicine MEDLINEPlus)
- National Center for Immunization and Respiratory Diseases (Centers for Disease Control and Prevention)

News

- Rotavirus Unopposed and Covered Under the VICP
- Influenza Vaccines Covered Added as of July 1, 2006
- Hepatitis A Vaccines Added as of December 1, 2004

Individuals thought to be injured by these vaccines are eligible for compensation from the VICP as of their respective effective dates. This coverage permits people who think that they have been injured by these vaccines to file a claim for compensation

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- Brochure in English
- Booklet in English
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- Booklet in Spanish

HRSA

National Vaccine Injury Compensation Program

Covered Vaccines
Persons Eligible to File a Claim
Filing a Claim with the VICP
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Vaccine Injury Table list of vaccines and associated injuries covered under the program
Frequently Asked Questions
Statistics Reports
Strategic Plan
Advisory Commission on Childhood Vaccines (ACCV)
Contact Information

Filing Deadlines

The general filing deadlines are:

- For an *injury*, your claim must be filed within 3 years after the first symptom of the vaccine injury.
- For a *death*, your claim must be filed within 2 years of the death and 4 years after the start of first symptom of the vaccine-related injury from which the death occurred.

When a *new* vaccine is covered by the VICP or when a *new injury/condition* is added to the Vaccine Injury Table (Table), claims that do not meet the general filing deadlines must be filed within 2 years from the date the vaccine or injury/condition is added to the Table for injuries or deaths that occurred up to 8 years before the Table change. The Table lists and explains injuries that are presumed to be caused by vaccines. For details about the Table, go to Vaccine Injury Table.

For example, the hepatitis A vaccine was covered by the VICP as of December 1, 2004. Under the general filing deadline for an injury, the claim must be filed within 3 years after the first symptom of the vaccine injury. However, claims that do not meet the general filing deadlines must be filed by December 1, 2006 for injuries or deaths that occurred on or after December 1, 1998.

As a general filing rule, for individuals who are filing a claim, the appropriate filing deadline is the one above that provides the most time to file an injury or a death claim.

UNITED STATES COURT OF FEDERAL CLAIMS
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No. 05-VV-01002-LB

MELISSA CLOER, M.D., PETITIONER

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT

[Dated: Apr. 13, 2007]

Exhibit 25

AFFIDAVIT OF MICHAEL A. MEYER, M.D.
(April 2007)

---

1. My name is Michael A. Meyer, M.D. I am a SUNY Buffalo Professor of Clinical Neurology and Nuclear Medicine. I am affiliated With the Jacobs Neurological Institute in Buffalo, New York. My professional address is 100 High Street in Buffalo, New York.

2. This affidavit is based upon my experience, training and education. This affidavit is based upon a reasonable degree of probability in the

field of Neurology. This affidavit is signed under penalty of perjury.

3. As stated before, I have had an opportunity to review the records of Melissa Cloer when she was a patient at University Hospital and Clinics. My affidavit testimony is based upon my personal knowledge, information and belief as well as my custom and practice. Likewise, my affidavit takes into account my education, training and experience. Moreover, I have spoken with Dr. Cloer and reviewed updated medical information, including diagnostic imaging studies, related to her condition.

4. By way of background, I received my BA degree from Columbia University in New York, New York and my M.D. degree from Albany Medical College in Albany, New York. My residency was at the Mayo Clinic in Rochester, Minnesota. I completed fellowships in Nuclear Medicine and PET at both the University of Pennsylvania and the University of Michigan. I am board certified in Neurology, Nuclear Medicine and Nuclear Cardiology. My clinical interests include Multiple Sclerosis, memory disorders, Nuclear Medicine and Neuro-oncology. My research interests include Multiple Sclerosis and Neuro-oncology.

5. Previously, I provided medical care and treatment to Dr. Melissa Cloer. At the time I treated her, she was a medical student at the University of Missouri and I was affiliated with University

Hospital & Clinics at the University of Missouri (Columbia). Her name was Melissa Myers at that time.

6. At the time I treated Dr. Cloer in 1998 and 1999, she had not yet been formally diagnosed with clinically definite multiple sclerosis (MS). There had been no brain MRI demonstration of clinically definite MS with multifocal demyelinating plaques as an unequivocal manifestation of multiple sclerosis during the time period I treated Dr. Cloer.

7. It is my understanding that the Court would like me to further address the medical issues in light of a recent case, Markovich v. Secretary of Health and Human Services, 2007 WL 507107 (C.A. Fed.) (February 20, 2007, case 06-5039). Although I am not an attorney, I will attempt to address the medical issues raised in this decision as they relate to Dr. Cloer.

8. It is my understanding that the Vaccine Act has language that requires a petition to be filed within 36 months of the "first symptom or manifestation of onset" of injury. The Markovich opinion provides the following description and definition of those terms:

"There is a difference between a "symptom" and "manifestation of onset." A symptom may be indicative of a variety of conditions or ailments and it may be difficult for lay persons to appre-

ciate the medical significance of a symptom with regard to a particular injury. A manifestation of onset is more self-evident of an injury and may include significant symptoms that clearly evidence an injury.

9. Given the Markovich decision states that " . . . ." the first . . . . manifestation of onset," for the purposes of § 300aa-16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large.", it follows that the November, 2003 Brain MRI could be considered as the first objective sign of a delayed vaccine related injury.

10. The literature on the topic of vaccines and demyelination is quite extensive, with post-vaccinal encephalomyelitis being a well described clinical phenomenon. A Pubmed.gov internet search revealed 1148 articles using the search term "vaccine demyelination", whereas "vaccine multiple sclerosis" continued to yield a significantly large literature of 359 articles; a convincing case report of a link between hepatitis B vaccine and objectively clear MR manifestations of MS has been published, and can be seen on line at the following URL address: http://www.cmj.org/Periodical/paperlist.asp?id=LW8451&linkintype=pubmed

11. Based on the available records and affidavits which I have reviewed, Dr. Cloer did not have a

diagnosis for clinically definite MS until approximately November of 2003.

12. Based on the available records and affidavits, Dr. Cloer's physician did not have MRI evidence of clinically definite until approximately November of 2003.

13. MS has been an important part of my professional activities. As such, I am probably more knowledgeable about MS than the medical profession at large.

14. It is my understanding that the Markovich decision, which I have been readily able to inspect and review through an internet search, contains the following language in the concluding paragraph that describes an "objective standard" regarding statute of limitations:

"For all of the reasons discussed above, we hold that 'the first symptom or manifestation of onset,' for the purposes of § 300aa-16(a)2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large."

The concluding paragraph of the Markovich decision goes on to state: " . . . Because the testimony of Dr. Corbier and others confirms that Ashlyn's eye blinking episode on July 10, 2000 was objectively recognizable by the medical profession at large as constituting the first evidence of vaccine injury onset, i.e., the first symptom of

injury, and because the Markoviches filed their petition on August 29, 2003, more than 36 months after the initial symptoms, the petition . . . "

15. Based on my knowledge of MS, the available records and affidavits, the medical profession at large would consider the first symptom or manifestation of onset of her MS to be in November 2003, when diagnostic information and Dr. Cloer's changed clinical picture became clinically definite MS as a result of the MRI brain scan images that became available. By analogy, the first manifestation for Dr. Cloer that was objective and definite to form a diagnosis for clinically definite MS was the November 2003 MRI (the "eye blinking" equivalent for manifestation in this particular case)

16. Based on my knowledge of MS, the available records and affidavits, the medical profession at large would not have found her to be firmly diagnosed with clinically definite MS until it became apparent on the November 2003 follow-up MRI examination of the brain. It is important to note that retrospective review of medical information provides a much different viewpoint than that acquired in a prospective manner, and that all clinical data prior to the Nov 2003 MRI was not specific enough to have categorized her problem as being clinically definite MS at that time. In retrospect, her clinical symptoms prior

to 2003 are now clearly viewed as being with consistent with but not independently diagnostic for clinically definite MS.

17. As I have tried to explain, as of 1998 and 1999, Dr. Cloer had experienced isolated events that, by themselves, were not MS. Even on a retrospective basis, the symptoms and signs were consistent with but not objectively diagnostic for MS. As of 1998 and 1999, Dr. Cloer had experienced medical events that could have never returned, never progressed of never developed into MS.

18. Based on my knowledge of MS, the available records and affidavits, the medical profession at large would not have considered Dr. Cloer to have sustained a vaccine injury until after November 2003 when the aggregate of newly directed scientific inquiry and further medical literature suggested a possible link of Hepatitis B vaccination to the multifocal demyelinating plaques seen on MRI as the first clear and objectively positive manifestation of her disease.

/s/ DR. MICHAEL A. MEYER [4/13/07]
DR. MICHAEL A. MEYER/SIGNATURE Date

[NOTARY PUBLIC STAMP OMITTED]

UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 05-VV-01002-LB
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MELISSA CLOER, M.D., PETITIONER

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, RESPONDENT

[Dated: Sept. 27, 2007]

Exhibit 26

AFFIDAVIT OF DR. MELISSA CLOER
(September 2007)

---

1. My name is Melissa Cloer and I am the Petitioner in a claim pending in the National Vaccine Injury Compensation Program.
2. The sworn affidavit testimony is based upon my personal knowledge and belief as well as a review of my medical records.
3. My testimony, to the extent is expresses opinions, is based upon a reasonable degree of probability.

4. I have been asked to address when any of the signs, the occurrence of the first symptom or manifestation of onset of my Multiple Sclerosis (MS) lasted six months or more.

5. It was not until late 2003 or early 2004 that any signs, first symptoms or manifestation of onset of my Multiple Sclerosis persisted for six months or more.

6. It was not until late 2003 or early 2004 that I experienced six months or more of fatigue.

7. I did not experience any other first signs, occurrence of manifestation of onset of my injury for a period of six months or more until the fatigue persisted for months or more in late 2003 or early 2004.

8. I did not suffer the residual effects or complications of any illness, disability, injury or condition related to my MS for more than a six months period until late 2003 or early 2004.

9. As attested to before, prior to late 2003 I did not have any persisting signs, symptoms or manifestation of onset of MS continue for six months or more. Rather, before late 2003, any signs or symptoms waxed, waned and/or resolved.

10. This affidavit is signed under penalty of perjury.

FURTHER AFFIANT SAYETH NOT:

/s/ MELISSA CLOER, MD [9/27/07]
MELISSA CLOER, MD /Signature Date

PETITIONER'S BRIEF

SUPREME COURT, U.S.
FILED
JAN 4 - 2013
CLERK

No. 12-236

In the Supreme Court of the United States

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

MELISSA CLOER

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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QUESTION PRESENTED

Whether a person whose petition under the National Vaccine Injury Compensation Program is dismissed as untimely may recover from the United States an award of attorneys' fees and costs.

PARTIES TO THE PROCEEDING

The caption of the case in this Court contains the names of all parties in the court of appeals.

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In the Supreme Court of the United States

No. 12-236

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

MELISSA CLOER

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE PETITIONER

ORDER AND OPINIONS BELOW

The order of the en banc court of appeals (Pet. App. 1a-21a) is reported at 675 F.3d 1358. A related opinion of the en banc court of appeals (Pet. App. 22a-83a) is reported at 654 F.3d 1322. A related opinion of a panel of the court of appeals (Pet. App. 88a-125a) is reported at 603 F.3d 1341. A related opinion of the United States Court of Federal Claims (Pet. App. 126a-154a) is reported at 85 Fed. Cl. 141. A related decision of the Chief Special Master of the United States Court of Federal Claims (Pet. App. 155a-176a) is not published in the *Federal Claims Reporter* but is available at 2008 WL 2275574.

JURISDICTION

The order of the en banc court of appeals was entered on April 11, 2012. On June 27, 2012, the Chief Justice

extended the time within which to file a petition for a writ of certiorari to and including August 9, 2012. On July 27, 2012, the Chief Justice further extended the time to August 23, 2012, and the petition was filed on August 22, 2012. The petition for a writ of certiorari was granted on November 20, 2012. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent provisions of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.*, and the Internal Revenue Code are reprinted in an appendix to this brief. App., *infra*, 1a-40a.

STATEMENT

This case presents the question whether a person whose claim under the National Vaccine Injury Compensation Program is dismissed as untimely may recover from the United States an award of attorneys' fees and costs. Dividing 7-to-6, the en banc Federal Circuit held that such awards are available.

1. a. To stabilize the vaccine market and provide compensation for vaccine-related injuries and deaths, Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), 42 U.S.C. 300aa-1 *et seq.* Congress determined that existing approaches to compensating people for injuries caused by vaccines—"through the civil tort system or through a settlement arrangement with the vaccine manufacturer"—were inadequate "from both the perspective of vaccine-injured persons as well as vaccine manufacturers." H.R. Rep. No. 908, 99th Cong., 2d Sess. 6-7 (1986) (*House Report*). Congress's study of the problem revealed in particular that "[l]awsuits and settlement negotiations can take months and even years to complete. Transaction costs—including attorneys' fees and

court payments—are high. And in the end, no recovery may be available." *Id.* at 6.

To address those concerns, Congress created the National Vaccine Injury Compensation Program (Compensation Program or Program), see 42 U.S.C. 300aa-10(a), "a Federal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity," *House Report* 3. Congress intended the Compensation Program to be "fair, simple, and easy to administer." *Id.* at 7. Its procedures are designed to secure an "expeditious and fair" outcome for claimants in the Program. *Id.* at 12. The Act creates a Vaccine Injury Table that identifies covered vaccines and particular injuries associated with them, and a causal connection between vaccine and injury is rebuttably presumed when a claim is based on an injury specified in the Table. *Shalala* v. *Whitecotton*, 514 U.S. 268, 270 (1995); 42 U.S.C. 300aa-14; 42 C.F.R. Pt. 100. If an injury falls outside the parameters of the Table, a claimant must prove that the injury "was caused by" the covered vaccine, 42 U.S.C. 300aa-11(c)(1)(C)(ii)(I) and (II), but need not establish that the vaccine was defective or that any person was at fault.

A person who claims to be injured by a vaccine (or the representative of such a person) may file a petition for compensation in the United States Court of Federal Claims (CFC), naming the Secretary of Health and Human Services (Secretary) as the respondent. *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011); 42 U.S.C. 300aa-11(c)(1)(C)(ii), 300aa-12(b)(1). A special master of the CFC then "makes an informal adjudication of the petition," *Bruesewitz*, 131 S. Ct. at 1073, subject to further review by a judge of the CFC and by the United States Court of Appeals for the Federal

Circuit, see 42 U.S.C. 300aa-12(e)(2)(B) and (f). "After judgment has been entered by the [CFC] or * * * after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa-11" must elect between accepting the CFC's judgment and pursuing a civil tort action instead. 42 U.S.C. 300aa-21(a); see *Bruesewitz*, 131 S. Ct. at 1073 & n.16.

"[T]o expedite the proceedings" in the Compensation Program, Congress "replace[d] the usual rules of discovery in civil actions in Federal courts" with more limited discovery conducted under the auspices of the special master. *House Report* 16. Congress also provided that the "[c]ompensation awarded under the Program may not include * * * [p]unitive or exemplary damages," 42 U.S.C. 300aa-15(d), thus limiting the issues before the special master to "whether the petitioner suffered a compensable injury and, if so, the extent of compensable damages." *House Report* 16. That limitation obviates the "need for a wider inquiry, which might be appropriate in a civil action raising other issues." *Ibid.* To ensure that "[t]he entire proceeding—from date of filing through Special Master proceedings and court review—is to take place as expeditiously as possible," *id.* at 17, Congress directed the court to "render its judgment * * * as expeditiously as practicable but not later than 365 days after the date on which the petition was filed," 42 U.S.C. 300aa-12(d)(3) (Supp. IV 1987).[1]

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[1] Congress later revised the Act to provide a series of time limits for the special master and reviewing court, and to permit the claimant to withdraw her petition if those deadlines pass without a decision. See 42 U.S.C. 300aa-12(d)(3)(C), (e)(2) and (g); *Bruesewitz*, 131 S. Ct. at 1073 & nn.13-14. In contemporary practice, petitions are typically resolved in two to three years. See Health Res. & Servs. Admin., U.S. Dep't of Health & Human Servs., *National Vaccine*

In every respect, the Act's no-fault compensation program thus is "designed to work faster and with greater ease than the civil tort system." *Bruesewitz*, 131 S. Ct. at 1073 (quoting *Whitecotton*, 514 U.S. at 269). "[M]uch of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the petitioner can expect judgment; without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner." *House Report* 17.

b. This case concerns the award of attorneys' fees and costs to a person whose claim under the Compensation Program was dismissed as untimely. The Vaccine Act's limitations provision states that "no petition may be filed for compensation under the program * * * after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of" the alleged injury for which compensation is sought. 42 U.S.C. 300aa-16(a)(2).

With respect to awards of attorneys' fees and costs, the Act provides:

> In awarding compensation on a petition filed under [42 U.S.C. 300aa-11] the special master or court shall also award as part of such compensation an amount to cover—
>
> (A) reasonable attorneys' fees, and
>
> (B) other costs,
>
> incurred in any proceeding on such petition. If the judgment of the [CFC] on such a petition does not

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Injury Compensation Program: Statistics Report n.1 (Dec. 3, 2012), http://www.hrsa.gov/vaccinecompensation/statisticsreports.html.

> award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

42 U.S.C. 300aa-15(e)(1).

Section 300aa-15(e)(1) differs from most fee-shifting provisions in that it does not make success on the underlying claim a prerequisite to an award of fees. Rather, so long as the special master or the court finds that a petition under Section 300aa-11 "was brought in good faith and there was a reasonable basis for the claim," the special master or the court may award reasonable attorneys' fees and costs even "[i]f the judgment * * * does not award compensation" to the claimant. 42 U.S.C. 300aa-15(e)(1). And because "[n]o attorney may charge any fee for services in connection with a petition filed under [42 U.S.C. 300aa-11] which is in addition to any amount awarded as compensation by the special master or court under [the fee shifting provision]," 42 U.S.C. 300aa-15(e)(3), the Vaccine Act's fee-shifting provision is the sole source of compensation for attorneys in those circumstances.

Awards of attorneys' fees and costs, like awards of compensation on the merits, are paid from the Vaccine Injury Compensation Trust Fund (Compensation Fund). 42 U.S.C. 300aa-15(f)(4)(A); see 26 U.S.C. 9510 (establishing Compensation Fund). The Compensation Fund is supported by a standing appropriation of "amounts equivalent to the net revenues received in the Treasury from the tax imposed by [26 U.S.C.] 4131" on each dose of vaccine covered by the Program. 26 U.S.C.

9510(b)(1); see 26 U.S.C. 4132(a)(1) (enumerating taxable vaccines). "Because of the straightforward nature of the petition and the proceedings," Congress did "not anticipate that reasonable attorneys' fees will be large." *House Report* 22. Rather, it expected that "[w]ith most evidentiary requirements specified in the legislation, with prohibitions on traditional discovery and courtroom procedure, and with no obligations to demonstrate negligence or product defectiveness, the costs of legal services will * * * approximate those incurred in" other such "no-fault, non-adversarial system[s] * * * as the Black Lung benefits program or workers' compensation programs." *Id.* at 36.

2. After receiving three Hepatitis-B immunizations in 1996 and 1997, respondent experienced in mid-1997 what proved to be her first symptom of multiple sclerosis (MS). Pet. App. 29a. On September 16, 2005, eight years after her first symptoms of MS, respondent filed a claim for compensation under the Vaccine Act. *Id.* at 31a; J.A. 16 (docket entry). The parties participated in an initial status conference six weeks after the petition was filed. J.A. 18 (docket entry). Five weeks later, the Secretary moved to dismiss respondent's claim as untimely, explaining that "[t]he record in this case establishes that [respondent] began experiencing neurologic symptoms of MS in 1997," but "did not file her petition until September 16, 2005, at least four years beyond the statutory deadline." Dkt. 7, at 6-7; J.A. 19 (docket entry).

The Chief Special Master ultimately agreed and dismissed respondent's claim as time-barred. Pet. App. 155a-176a. He explained that "[i]t is clear from the medical records, [respondent's] affidavits, as well as [respondent's treating neurologist's] affidavits and testi-

mony that the first symptom of the onset of [respondent's] MS was in 1997. Since the Petition was filed eight years later, the Petition was untimely." *Id.* at 168a. The CFC affirmed. *Id.* at 126a-154a.

3. a. A divided panel of the Federal Circuit reversed. Pet. App. 88a-125a. The panel held that the Vaccine Act's limitations period does not begin to run until there is objective medical recognition of a link between the claimed injury and the vaccine. *Id.* at 93a-102a. In respondent's case, the panel concluded, such recognition had occurred (if at all) no earlier than 2004. *Id.* at 102a.

b. The court of appeals granted the government's petition for rehearing en banc and affirmed the CFC's dismissal of respondent's claim as time-barred. Pet. App. 22a-83a. The en banc court rejected the panel's view that the Vaccine Act's statute of limitations is not triggered unless there is a medical recognition of a link between the claimed injury and the vaccine. The court held instead that, "[c]onsistent with the plain meaning of the statute, * * * the statute of limitations of the Vaccine Act begins to run on the calendar date of the occurrence of the first medically recognized symptom or manifestation of onset of the injury claimed by the petitioner." *Id.* at 23a-24a.

The en banc court of appeals further held that the Vaccine Act's statute of limitations is subject to equitable tolling, rejecting its longstanding view to the contrary, see *Brice* v. *Secretary of HHS*, 240 F.3d 1367, 1370-1374 (Fed. Cir.), cert. denied, 534 U.S. 1040 (2001). Pet. App. 24a. But the court went on to conclude that respondent had failed to identify a sound basis for tolling in her case. Focusing on traditional circumstances warranting equitable tolling, the court explained that respondent "has put no argument before this court that,

for example, she has been the victim of a fraud, or of duress." *Id.* at 65a. Respondent contended that applying the Act's time limits "is *ipso facto* unfair because it threatens to deprive her of her claim." *Ibid.* The court concluded that this was "not * * * the sort of circumstance that might merit equitable tolling." *Ibid.*

c. This Court denied respondent's petition for a writ of certiorari seeking review of the court of appeals' holding that her claim was time-barred. 132 S. Ct. 1908 (No. 11-832). The government's brief in opposition to that certiorari petition explained (at 17-19) that, although the government disagreed with the court of appeals' decision to recognize equitable tolling of the Act's limitations period, respondent's case did not present a suitable vehicle for resolving that issue.

4. Respondent moved in the court of appeals for an award of $118,792.95 in attorneys' fees and costs for proceedings in the Federal Circuit. Pet. App. 4a; No. 2009-5052 Docket entry No. 74 (Sept. 6, 2011) (application for award of attorneys' fees and costs); *id.* No. 75 (Sept. 12, 2011) (supplement to application). By a 7-6 vote, the court of appeals held that the dismissal of respondent's complaint as untimely did not preclude the possibility of a fee award under the Act. The court remanded respondent's fee motion for a determination whether respondent's claim had been brought in good faith and with a reasonable basis. Pet. App. 1a-12a.

a. Overruling circuit precedent to the contrary, see *Brice* v. *Secretary of HHS*, 358 F.3d 865, 868-869 (Fed. Cir. 2004), the seven-member majority of the en banc court of appeals held that a person who files an untimely Vaccine Act petition, but who "assert[s] a reasonable limitations argument" in connection with that claim, is eligible for an award of attorneys' fees and costs "absent

a determination that [the] petition was not brought in good faith or that the claim for which the petition was brought lacked a reasonable basis." Pet. App. 5a. The majority held "that Congress did not intend to require compliance with [the Act's limitations provision] as a prerequisite for the recovery of attorneys' fees." *Id.* at 6a. Rather, the majority concluded, "[t]he good faith and reasonable basis requirements apply to the claim for which the petition was brought; this applies to the entire claim, including timeliness issues." *Id.* at 9a.

The en banc majority recognized that, under 42 U.S.C. 300aa-15(e), a Vaccine Act fee award is available only in a case involving "a petition filed under section 300aa-11." Pet. App. 6a. It also acknowledged the directive in 42 U.S.C. 300aa-16(a) that "no petition may be filed for compensation under the Program" after the Act's limitations period has expired. Pet. App. 10a. The majority concluded, however, that for purposes of the Vaccine Act's attorneys' fees provision, an untimely petition qualifies as a "petition filed under section 300aa-11." *Id.* at 6a-7a.

In support of that conclusion, the en banc majority observed that Vaccine Act proceedings can be initiated only by the filing of a petition. Pet. App. 5a (citing 42 U.S.C. 300aa-11(a)(1)). The majority inferred from that fact that "[u]nless * * * [respondent's] filing was a 'petition filed,' neither we nor the [CFC] had jurisdiction over her appeal." *Id.* at 5a-6a. The majority also explained that another provision of the Vaccine Act (42 U.S.C. 300aa-11(a)(2)(A), relating to the conditions for filing a civil suit under state law) expressly cross-references the limitations provision. Pet. App. 6a. The majority stated that "[t]he absence of an analogous reference to [42 U.S.C.] 300aa-16 in the attorneys' fees

provision suggests that Congress did not intend to require compliance with [42 U.S.C.] 300aa-16 as a prerequisite for the recovery of attorneys' fees." *Ibid.* The majority also noted that the term "petition filed" is used in other Vaccine Act provisions and, in context, appears to encompass untimely petitions. *Id.* at 6a-7a.

The en banc majority also stated that "[r]emedial legislation like the Vaccine Act should be construed in a manner that effectuates its underlying spirit and purpose." Pet. App. 8a. The majority expressed the view that its interpretation of the Act's fee provision would "fulfill[] congressional intent and the Act's legislative purpose" because "having to shoulder attorneys' fees could deter victims of vaccine-related injuries from seeking redress." *Ibid.* The court of appeals remanded to the CFC for a determination "whether [respondent's] petition was brought in good faith and whether the claim for which her petition was brought had a reasonable basis." *Id.* at 12a.

b. Judge Bryson, writing for six judges, dissented. Pet. App. 13a-21a. He explained that "[42 U.S.C. 300aa-16(a)] directs that 'no petition may be filed for compensation under the Program'—and thus under [42 U.S.C. 300aa-11]—after the expiration of the applicable time period." Pet. App. 14a. He further observed that "[42 U.S.C. 300aa-15(e)(1)] allows an attorneys' fee award only when a petition is filed under [42 U.S.C. 300aa-11]." Pet. App. 14a. The dissenting judges would have held on that basis that "an attorneys' fee award may be made only if the claimant files a timely petition, either by satisfying the applicable limitations period of [42 U.S.C. 300aa-16] or successfully invoking equitable tolling." Pet. App. 14a (citations omitted).

Judge Bryson noted as well that "it is almost unknown in American practice for a statute to provide that the prevailing party will pay the losing party's attorneys' fees." Pet. App. 18a (citing *Ruckelshaus* v. *Sierra Club*, 463 U.S. 680, 683-684 (1983)). He reasoned that, "because Congress departed from the governing principles applied in virtually every other federal fee-shifting statute, [the court] should be cautious in interpreting the statutory mandate to extend beyond those cases in which fee-shifting was clearly intended." *Id.* at 19a (citing *Robert C. Herd & Co.* v. *Krawill Mach. Corp.*, 359 U.S. 297, 304-305 (1959)).

Judge Bryson also expressed concern about the practical difficulties that would arise in deciding a claim for attorneys' fees in a case dismissed on threshold timeliness grounds. He explained that, because Vaccine Act fees are available only for petitions brought in good faith and with a reasonable basis, the special master in such a fee proceeding would be required to conduct "a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding." Pet. App. 20a. He observed that "[q]uite apart from the burden on the special masters and the court, the amount of attorney time (and thus the accumulating fees) that would be consumed by such a proceeding would likely exceed the fees expended on the typically much simpler question whether equitable tolling is available to the claimant." *Id.* at 20a-21a. Judge Bryson reasoned that "it seems unlikely that Congress envisioned such a scheme, and in the absence of express congressional authorization, we should be cautious about engrafting one onto the statute." *Id.* at 21a.

SUMMARY OF ARGUMENT

A. The text of the Vaccine Act does not authorize an award of attorneys' fees and costs when the underlying petition for compensation has been dismissed as untimely. One statutory prerequisite for a fee award is "a petition filed under section 300aa-11 of" Title 42. 42 U.S.C. 300aa-15(e)(1). Because the Act's limitations provision states that "no petition may be filed for compensation under the Program" after the applicable time limit expires, 42 U.S.C. 300aa-16(a)(2), a petition that has been dismissed as untimely is not a "petition filed under section 300aa-11." Respondent and the majority below rely heavily on the fact that, while some Vaccine Act provisions contain express cross-references to the Act's limitations provision, the Act's fee-shifting provision (Section 300aa-15(e)(1)) does not. A specific cross-reference to the limitations provision was unnecessary, however, because Section 300aa-15(e)(1) itself expressly requires "a petition filed under section 300aa-11," and an untimely petition does not fit that description.

B. Awarding attorneys' fees and costs on untimely petitions would be incompatible with the streamlined Compensation Program that the Vaccine Act establishes. Untimely Vaccine Act petitions will often be dismissed with little or no inquiry by the special master into the merits of the claimant's request for compensation. If fees and costs were available for untimely petitions, the determination whether particular claims were brought in "good faith" and with a "reasonable basis" on the merits, 42 U.S.C. 300aa-15(e)(1), would require "a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding," Pet. App. 20a (Bryson, J., dissenting).

Such "shadow trials" would be substantially more arduous than the usual Vaccine Act fee proceeding, which is conducted by a special master who has already studied and resolved the pertinent merits issues, and they would divert substantial resources to proceedings that can be of no benefit to the claimants themselves. The availability of fees for untimely petitions would also likely cause more such petitions to be filed, further diverting Program resources to ancillary fee litigation and untimely claims, and away from the provision of compensation to injured claimants. Although the Vaccine Act's fee-shifting provision was intended to create incentives for attorneys to represent claimants, limiting fee and cost awards to timely petitions would best respect both those incentives and Congress's desire to establish a Compensation Program that functions simply and smoothly.

C. To the extent that the relevant Vaccine Act provisions are ambiguous, applicable canons of statutory construction reinforce the conclusion that attorneys' fees and costs may not be awarded on untimely petitions. Vaccine Act fee awards directly implicate the principle that waivers of sovereign immunity are to be narrowly construed. Interpreting the Act to allow fee awards on untimely petitions would also substantially depart from the common law principles that have traditionally governed the question of who bears responsibility for legal expenses. And construing the Act to avoid lengthy and complex fee proceedings would respect this Court's admonition that a "request for attorney's fees should not result in a second major litigation." *Hensley* v. *Eckerhart*, 461 U.S. 424, 437 (1983).

D. The en banc majority's other rationales for its construction of the Vaccine Act's fee provision are un-

persuasive. A recognition that a Vaccine Act petition must be timely in order to qualify as a "petition filed under section 300aa-11" would not create anomalous results or impede the resolution of Vaccine Act cases. And prior Federal Circuit decisions allowing "interim" fee awards in Vaccine Act cases do not support the result here, both because those decisions are themselves contrary to the text of the Act, and because those decisions did not involve untimely claims.

ARGUMENT

A VACCINE ACT CLAIMANT WHOSE PETITION FOR COMPENSATION IS DIMISSED AS UNTIMELY MAY NOT RECOVER FROM THE UNITED STATES AN AWARD OF ATTORNEYS' FEES AND COSTS

Under the most straightforward reading of the Vaccine Act's limitations and attorneys' fees provisions, an award of attorneys' fees and costs is unavailable when a petition is dismissed as time-barred. The cumbersome regime that respondent's interpretation of the Act produces—under which a special master must conduct "a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding," Pet. App. 20a (Bryson, J., dissenting)—has no place in a compensation system "designed to work faster and with greater ease than the civil tort system." *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011) (quoting *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995)). Applicable canons of statutory construction reinforce the conclusion that fee awards are unavailable in these circumstances. The court of appeals' contrary decision should be reversed.

A. The Text Of The Vaccine Act Does Not Permit An Award Of Attorneys' Fees And Costs On An Untimely Petition

1. The Vaccine Act requires the special master to award attorneys' fees and costs when "awarding compensation on a petition filed under section 300aa-11 of this title." 42 U.S.C. 300aa-15(e)(1). The Act permits (but does not require) an award of fees and costs "[i]f the judgment * * * on *such a petition* does not award compensation." *Ibid.* (emphasis added). Because the phrase "such a petition" refers back to "a petition filed under section 300aa-11 of this title," the propriety of awarding attorneys' fees and costs on an untimely Vaccine Act petition depends on whether an untimely petition is a "petition filed under section 300aa-11." Respondent concedes that is the relevant textual question in this case. See Br. in Opp. 5 (quoting Pet. 11).

The Vaccine Act's limitations provision states that, "if a vaccine-related injury occurred as a result of the administration of [a covered] vaccine, *no petition may be filed* for compensation under the Program for such injury" after the expiration of the applicable time period. 42 U.S.C. 300aa-16(a)(2) (emphasis added). Because compliance with the limitations provision is a statutory prerequisite to the filing of a petition "for compensation under the Program," a petition that has been dismissed for failure to comply with the Act's time limits is not a "petition filed under section 300aa-11." And in the absence of a petition filed under Section 300aa-11, there is no statutory basis for awarding attorneys' fees and costs. See Pet. App. 14a (Bryson, J., dissenting).

2. In contesting this straightforward reading of the Vaccine Act, respondent (Br. in Opp. 6-8) and the majority below (Pet. App. 6a) rely heavily on the fact that 42 U.S.C. 300aa-11(a)(2)(A) (which addresses the circum-

stances under which a civil action may be filed against private parties after proceedings under the Compensation Program have concluded) expressly cross-references the limitations provision, while 42 U.S.C. 300aa-11(a)(1) (the provision for initiating a compensation proceeding) and 42 U.S.C. 300aa-15(e)(1) (the attorneys' fees and costs provision) do not. Respondent and the majority below would infer from that difference that Congress must have intended only the first of those provisions, and not the second or third, to depend on compliance with the limitations provision. That inference is unfounded for several reasons.

To begin with, as explained above, the Vaccine Act *does* link an award of attorneys' fees and costs to timeliness through cross-references—just not the particular one respondent would insist upon. By its terms, the fee-shifting provision requires "a petition filed under section 300aa-11," see 42 U.S.C. 300aa-15(e)(1), and the limitations provision states that "no petition may be filed" after the expiration of prescribed time periods, 42 U.S.C. 300aa-16(a)(2). The fee-shifting provision's requirement of "a petition filed under section 300aa-11" thus obviates the need for other cross-references to the limitations provision.

That statutory arrangement is analogous to the one this Court recently confronted in *Astrue* v. *Capato*, 132 S. Ct. 2021 (2012). Respondent's insistence on a particular form of cross-reference here is likewise analogous to the respondent's argument in *Capato*, which the Court rejected. See *id.* at 2031 ("Respondent notes the absence of any cross-reference in § 416(e) to § 416(h). She overlooks, however, that § 416(h) provides the crucial link * * * [by making] reference to 'this subchapter' [which] includes * * * [§] 416(e). Having explicitly

complemented § 416(e) by the * * * provisions contained in § 416(h), Congress had no need to place a redundant cross-reference in § 416(e).") (citation omitted).

More broadly, the negative inference respondent would draw from the absence of a particular form of cross-reference in Section 300aa-11(a)(1) proves too much. Section 300aa-11(a)(2)(A) is one of only a handful of provisions in the Vaccine Act that expressly reference the limitations provision. If an express cross-reference to the limitations provision were needed to trigger its application, the limitations provision would not apply in a broad array of circumstances. On respondent's logic, for example, a failure to comply with the limitations provision would not even bar recovery under the Compensation Program itself because 42 U.S.C. 300aa-13 ("Determination of eligibility and compensation") does not expressly cross-reference the limitations provision. No such problems arise on the government's reading.

Congress had sound reasons, moreover, to include the express cross-reference in Section 300aa-11(a)(2)(A). That section is a key part of Congress's "design[] to stabilize the vaccine market" through "significant tort-liability protections for vaccine manufacturers." *Bruesewitz*, 131 S. Ct. at 1074 & n.24 (citing 42 U.S.C. 300aa-11(a)(2)). In particular, Section 300aa-11(a)(2)(A) requires that a vaccine-injured person exhaust her remedies under the Compensation Program—and do so in a timely manner—before pursuing certain civil damage claims "in a State or Federal court" against the vaccine's administrator or manufacturer. Congress anticipated that the Program would thereby "divert a significant number of potential plaintiffs from litigation" against vaccine manufacturers. *House Report* 13.

In at least two ways, the express cross-reference in Section 300aa-11(a)(2)(A) is uniquely suited to the purpose of that provision. First, Section 300aa-11(a)(2)(A) has preemptive effect: It is a federal law that bars an otherwise permissible state-law suit from proceeding. Section 300aa-11(a)(2)(A)'s specific reference to the limitations provision confirms that preemption of any contrary state-law rule governing the prerequisites to filing a civil action under state law was "the clear and manifest purpose of Congress." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Second, unlike most of the Vaccine Act—which is addressed to expert special masters and to expert agencies within the federal government—Section 300aa-11(a)(2) is addressed to "a State or Federal court" with general jurisdiction over civil claims. The convenience and clarity of the express cross-reference in that provision makes it unnecessary for such generalist courts to familiarize themselves with the intricacies of the Vaccine Act, when they are called upon only to apply a straightforward rule about timely exhaustion of remedies under the Act.

Even if there were an unexplained discrepancy between Section 300aa-11(a)(1) and Section 300aa-11(a)(2)(A), that discrepancy would be an insufficient reason to adopt respondent's position. Congress often employs language "'out of an abundance of caution'" and "to remove any doubt" on an issue. *Ali* v. *Federal Bureau of Prisons*, 552 U.S. 214, 226 (2008) (quoting *Fort Stewart Schs.* v. *FLRA*, 495 U.S. 641, 646 (1990)). At a minimum, respondent's interpretation of the Vaccine Act is not so "plain" (Br. in Opp. 9) that this Court should ignore the structural features of the statute (see pp. 20-27, *infra*) and the canons of construction (see pp.

28-34, *infra*) that cut so sharply against her interpretation and in favor of the government's reading.

B. Awarding Attorneys' Fees And Costs On An Untimely Petition Is Incompatible With The Structure And Purpose Of The Vaccine Act

Respondent's position is also incompatible with the structure and overall purpose of the Vaccine Act. Congress sought to establish a simple and efficient procedural mechanism for providing compensation to persons injured by vaccines. See pp. 2-5, *supra*. Accepting respondent's position, by contrast, would necessitate complex proceedings that cannot possibly result in compensation for injured persons.

1. a. In a case in which the judgment does not award compensation, a fee award is authorized only for a claim "brought in good faith" and with a "reasonable basis." 42 U.S.C. 300aa-15(e)(1). As Judge Bryson explained in dissent below, "[i]n a case that has gone to judgment on the merits and the [Vaccine Act] petitioner has lost, it is fairly easy for the special master and the court to determine whether the petitioner's position on the merits was reasonable," because "the special master and the court will have the entire record of the case before them to enable them to make that determination." Pet. App. 20a. The special master who has studied and resolved the pertinent merits issues can apply the knowledge acquired during that endeavor in deciding whether an award of attorneys' fees and costs is warranted. The special master is thus in a position similar to that of a district judge who has decided a case on the merits adversely to the government, and is therefore well-situated to determine whether the government's position was "substantially justified" under the Equal Access to Justice Act (EAJA), 28 U.S.C. 2412(d). See

Pierce v. *Underwood*, 487 U.S. 552, 560 (1988) (noting that a district judge deciding a request for EAJA fees has "full knowledge of the factual setting" and, by dint of experience with the case, "may have insights not conveyed by the record").

By contrast, a Vaccine Act petition submitted after the Act's limitations period has expired may be dismissed on threshold grounds without any meaningful analysis of the merits. Indeed, the very nature and purpose of a limitations defense is that it ordinarily eliminates any need to inquire into the substance of a plaintiff's claim. See, *e.g.*, *Ritchey* v. *Upjohn Drug Co.*, 139 F.3d 1313, 1319 (9th Cir.), cert. denied, 525 U.S. 963 (1998). Under the Vaccine Act in particular, a special master conducting a limitations analysis typically needs only to determine "the date of the occurrence of the first symptom or manifestation of onset" of the claimed injury. 42 U.S.C. 300aa-16(a)(2). Thus, in respondent's case, "[t]he sole issue presented" to the special master concerned the date of respondent's first symptom of MS. Pet. App. 157a; see *id.* at 168a. The parties did not litigate, and the special master was not called upon to decide, whether respondent could establish her case on the merits—either as an injury within the parameters of the Table (which respondent did not assert) or as an injury caused in fact by a covered vaccine. Those issues will ordinarily go unaddressed when a Vaccine Act petition is dismissed as untimely.

Under those circumstances, the special master will have amassed no record, and will have acquired no case-specific expertise, that can be used to determine whether the claim was brought in "good faith" and had a "reasonable basis" on the merits. 42 U.S.C. 300aa-15(e)(1). To decide whether the claimant could satisfy those stat-

utory prerequisites for a fee award, the special master therefore would be required to "conduct a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding." Pet. App. 20a (Bryson, J., dissenting). The special master would also need to decide whether the claimant had offered a reasonable (albeit insufficient) basis for arguing either that the petition had been timely under the statutory deadline, or that the deadline should have been equitably tolled. See *id.* at 12a (majority opinion) (establishing threshold requirement of "an unsuccessful but non-frivolous limitations claim").

b. Such a collateral proceeding would be wasteful, painful, and complex—the antithesis of the system that Congress "designed to work faster and with greater ease than the civil tort system." *Bruesewitz*, 131 S. Ct. at 1073 (quoting *Whitecotton*, 514 U.S. at 269). Proceedings to decide whether there was a reasonable basis for a claim (had it been timely) would consume much of the effort that actually deciding the claim would have entailed, undermining the resource-conserving purpose of the limitations provision. Such proceedings would typically include review of the claimant's medical records, development of expert testimony, and briefing to the special master. Cf., *e.g.*, *Perreira* v. *Secretary of HHS*, 33 F.3d 1375, 1377 (Fed. Cir. 1994) (applying the "reasonable basis" requirement in an objective fashion taking into account the evidence offered in support of the Vaccine Act petitioner's merits claim). In cases where the special master held that a fee award was appropriate, the award could include attorneys' fees and costs for the fee proceedings themselves. See Pet. App. 20a-21a (Bryson, J., dissenting) (predicting that the amount of

attorney time and consequent fees attributable to fee proceedings in this situation typically will be greater than the fees incurred while litigating the original timeliness question). That effort and those expenses, moreover, would be incurred *after* it had been definitively determined that the claimant was not entitled to compensation.

This shadow trial would be thoroughly unappealing to the claimant herself. Vaccine Act claimants often suffer from debilitating diseases or conditions that require lifelong intensive medical care and are sometimes terminal. Yet the attorneys' fee inquiry would call on the claimant to further expose her medical records (and perhaps herself) to examination by a new round of experts, and face a trial of sorts. Similarly, the claimant's family members (who not uncommonly testify in proceedings on the merits) could be called upon to participate in fee proceedings. To be sure, a claimant who seeks Vaccine Act compensation must accept similar burdens in connection with the resolution of her claim on the merits. But while such merits proceedings may culminate in an actual award of compensation, the shadow trials that respondent's position would require can produce no tangible benefit for claimants themselves, only for their lawyers.

Moreover, the determination whether a claimant had reasonable arguments as to both timeliness and the merits can be particularly delicate and complex in Vaccine Act cases because there will sometimes be tension between a claimant's merits and timeliness theories. To establish that a particular medical condition resulted from administration of a covered vaccine, it is typically helpful to show that the first manifestations of the condition were perceived soon after the vaccine was admin-

istered. See, *e.g.*, *Althen* v. *Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (explaining that a "showing of a proximate temporal relationship between vaccination and injury" tends to support a claim under the Vaccine Act). But because the Vaccine Act's limitations period begins to run on "the date of the occurrence of the first symptom or manifestation of onset" of the pertinent condition, 42 U.S.C. 300aa-16(a)(2), a claimant's effort to establish that her petition was timely filed will often involve an attempt to dispute the relevance of any early-occurring symptom (as respondent did here, see Pet. App. 173a-174a). Thus, in considering a fee request after dismissal of an untimely Vaccine Act petition, a special master would need to determine not only whether the claimant had reasonable arguments on both timeliness and the merits, but also whether those arguments were internally consistent.

The facts of *Smith* v. *Secretary of HHS*, No. 02-93V, 2006 WL 5610517 (Fed. Cl. July 21, 2006), sustained, 2006 WL 5624674 (Fed. Cl. Nov. 16, 2006), aptly illustrate the problems that would arise during shadow trials. There, the Vaccine Act petitioner alleged that her son had developed diabetes as a result of a series of vaccinations ending in late 1998. *Id.* at *1-*2. In January 1999, the boy experienced symptoms including excessive thirst and frequent urination. *Id.* at *2, *6. In February 1999, the boy was hospitalized with dangerously high blood sugar and diagnosed with diabetes. *Id.* at *2. The Vaccine Act petition was filed in late January 2002, within the 36-month limitations period as measured from the hospitalization and diagnosis of diabetes, but outside the period as measured from the earlier symptoms. *Id.* at *2-*3. The claim was held to be time-barred, based on the special master's finding that the

earlier symptoms were "the first symptom or manifestation of onset," 42 U.S.C. 300aa-16(a)(2), of the boy's diabetes. 2006 WL 5610517, at *7.

Under the government's approach, no fee award would be available in *Smith*. And indeed, no attorneys' fees or costs were awarded in *Smith* because, until the decision below, the Federal Circuit had held that an award of attorneys' fees and costs was unavailable when a Vaccine Act petition was dismissed as untimely. *Brice* v. *Secretary of HHS*, 358 F.3d 865, 868-869 (2004) (*Brice II*); cf. *Martin* v. *Secretary of HHS*, 62 F.3d 1403, 1405-1407 (Fed. Cir. 1995) (holding that Vaccine Act attorneys' fees were unavailable because the claimants' prior civil suit had foreclosed the special master from asserting jurisdiction over their underlying Vaccine Act petitions).

By contrast, under respondent's approach, resolving whether the claimant in *Smith* was entitled to an award of attorneys' fees and costs would entail a collateral proceeding to determine whether there was a reasonable basis for believing that the boy's vaccinations in 1998 caused diabetes that was first manifested in February 1999, with coincidental and unrelated symptoms of excessive thirst and frequent urination in January 1999. That inquiry is substantially more complex than the inquiry the special master would have conducted if the claim had been timely (*viz.*, simply whether there was a reasonable basis for a claim that the boy's vaccinations caused his diabetes). "[I]t seems unlikely that Congress envisioned such a scheme, and in the absence of express congressional authorization," the court of appeals should not have "engraft[ed] one onto the statute." Pet. App. 21a (Bryson, J., dissenting).

c. Because "challenges brought on limitations grounds will frequently arise in vaccine injury cases," Pet. App. 11a, accepting respondent's position would likely have two broad and adverse effects on the Compensation Program.

First, the "shadow trials" described above, pp. 21-25, *supra*, can be expected to consume substantial resources of the special masters, reviewing courts, and others involved in the Compensation Program. As outlined above, fee proceedings on untimely petitions are likely to be more elaborate and time-consuming than on petitions where judgment has been entered on the merits. That is a particularly unwarranted and wasteful allocation of the Compensation Program's resources because the cases affected by the question presented are by definition cases in which the claimant will not receive compensation. "A request for attorney's fees should not result in a second major litigation." *Hensley* v. *Eckerhart*, 461 U.S. 424, 437 (1983). But the decision below promises exactly that.

Second, the inducement of a fee award to claimants' counsel is likely to increase the number of untimely Vaccine Act petitions. To be sure, the extent of that increase cannot reliably be predicted in advance. The basic purpose of fee-shifting provisions, however, is to increase the incentives for attorneys to provide services in particular categories of cases, thereby enhancing the ability of potential litigants to obtain representation. See, *e.g.*, *Pennsylvania* v. *Delaware Valley Citizens' Council for Clean Air*, 478 U.S. 546, 559-560 (1986). Because awards of attorneys' fees and costs on untimely Vaccine Act petitions had not been available prior to the decision below, see *Brice II*, *supra*, an increase in the number of untimely Vaccine Act petitions would be the

natural and expected result of affirming the court of appeals' new position that attorneys who file such petitions are eligible for an award of fees.

Because the Program's resources are limited—there is, for example, a statutory cap on the number of special masters, 42 U.S.C. 300aa-12(c)(1)—effort devoted to collateral matters can be expected to impede the prompt resolution of meritorious claims for much-needed compensation. The Act reflects Congress's effort to establish a compensation system "designed to work faster and with greater ease than the civil tort system." *Bruesewitz*, 131 S. Ct. at 1073; see *House Report* 3 (explaining that the Act establishes a "compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity"); *id.* at 17 ("[M]uch of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the [Vaccine Act] petitioner can expect judgment," and "without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner"). A rule that forces special masters, reviewing courts, and others to devote extensive resources to fee litigation and untimely claims, rather than to the merits of timely filed petitions, would subvert the Act's basic design.

2. The majority below took a different view of the Act's structure and purposes. The en banc court stated that "[r]emedial legislation like the Vaccine Act should be construed in a manner that effectuates its underlying spirit and purpose." Pet. App. 8a. The court concluded that awards of attorneys' fees and costs for untimely petitions were [illegible]ropriate because withholding such

awards "could deter victims of vaccine-related injuries from seeking redress." *Ibid.*

The general proposition underlying that reasoning is unhelpful in deciding this case because "[n]o legislation pursues its purposes at all costs, and [e]very statute purposes, not only to achieve certain ends, but also to achieve them by particular means." *Freeman* v. *Quicken Loans, Inc.*, 132 S. Ct. 2034, 2044 (2012) (second pair of brackets in original) (internal quotation marks and citations omitted). Here, the relevant provisions of the Vaccine Act obviously limit the availability of a claimant's remedies, including by barring untimely claims irrespective of merit. And while the incentives created by the Vaccine Act's fee-shifting provisions are undoubtedly part of Congress's remedial design, Congress had other values in mind as well—such as ensuring the simplicity and smooth functioning of the Compensation Program—which is why an award of attorneys' fees and costs is available only in specified circumstances, *i.e.*, on a successful petition or an unsuccessful petition filed in good faith with a reasonable basis. See 42 U.S.C. 300aa-15(e)(1). This case simply calls for recognition that, in the service of those other values, see pp. 20-27, *supra*, timely filing is among the conditions Congress placed on the availability of an award of attorneys' fees and costs.

C. Applicable Canons Of Statutory Construction Reinforce The Conclusion That Attorneys' Fees And Costs Are Not Available When A Vaccine Act Petition Is Dismissed As Untimely

For the reasons stated above, respondent's position is inconsistent with the text and structure of the Vaccine Act. To the extent that the Vaccine Act is ambiguous on this point, established canons of statutory construction should inform this Court's understanding of the Act's

fee-shifting provision. Three such canons reinforce the conclusion that fees are not available when a Vaccine Act petition is dismissed as untimely.

1. Principles of sovereign immunity disfavor the recovery of attorneys' fees and costs from the United States on an untimely Vaccine Act petition

a. The Vaccine Act authorizes monetary claims against the United States by way of a suit against the Secretary in her official capacity. See 42 U.S.C. 300aa-12(b)(1) ("[T]he Secretary shall be named as the respondent."); 42 U.S.C. 201(c) (defining "Secretary" as "the Secretary of Health and Human Services"). In Compensation Program proceedings, the Secretary is "represented in accordance with section 518(a) of title 28," 42 U.S.C. 300aa-12(b)(1), which provides for the Attorney General to "conduct and argue * * * suits in the [CFC] * * * in which the United States is interested," 28 U.S.C. 518(a). A Vaccine Act claim therefore is a suit against the United States.

"Caution is especially warranted in a case authorizing a monetary award against the government in light of well-settled principles of sovereign immunity." Pet. App. 21a (Bryson, J., dissenting). That principle applies even when (as in the Vaccine Act) Congress has unambiguously waived sovereign immunity from *some* monetary claims. See, *e.g.*, *FAA* v. *Cooper*, 132 S. Ct. 1441, 1448 (2012) ("For the same reason that we refuse to enforce a waiver that is not unambiguously expressed in the statute, we also construe any ambiguities in the scope of a waiver in favor of the sovereign."). Accordingly, the scope of the Vaccine Act's waiver of sovereign immunity—including the United States' liability to pay respondent's attorneys' fees and costs—should be strictly construed. *E.g.*, *United States* v. *Nordic Vill. Inc.*,

503 U.S. 30, 34 (1992) ("[T]he Government's consent to be sued must be construed strictly in favor of the sovereign and not enlarged beyond what the language requires.") (alterations, citations, and internal quotation marks omitted).

b. Respondent has "question[ed] whether the Vaccine Act involves a true waiver of sovereign immunity." Br. in Opp. 15. She relies on the fact that excise taxes paid on each dose of a covered vaccine (26 U.S.C. 4131, 4132) are effectively deposited into the Compensation Fund in the Treasury (26 U.S.C. 9510), which is used to pay awards under the Compensation Program (42 U.S.C. 300aa-15(f)(4)(A)). Respondent has contended that, because this framework could be analogized to commercial insurance premiums paid into a fund used by the insurer to pay claims, sovereign immunity principles do not apply to the Compensation Fund.

That argument is misconceived because the Compensation Program is not commercial insurance. Rather—as with many federal programs that involve federal funds and are subject to principles of sovereign immunity—the Compensation Program raises money through Congress's "Power To lay and collect * * * Excises," U.S. Const. Art. I, § 8, Cl. 1; the Treasury holds that money for the benefit of the United States; and funds are disbursed "in Consequence of Appropriations made by Law," *id.* § 9, Cl. 7, to claimants to "provide for the * * * general Welfare of the United States," *id.* § 8, Cl. 1.

In particular, 26 U.S.C. 4131 imposes an excise tax on each dose of covered vaccine. Those taxes are received by the Treasury as revenue. To avoid the need for periodic appropriations of lump sums to pay awards under the Compensation Program, Congress has "appropriat-

ed to the Vaccine Injury Compensation Trust Fund amounts equivalent to the net revenues received in the Treasury from the tax imposed by [S]ection 4131." 26 U.S.C. 9510(b)(1). Confirming the limited nature of the Vaccine Act's waiver of sovereign immunity, the United States' liability under the Compensation Program is limited to amounts so appropriated to the Compensation Fund. See 26 U.S.C. 9510(d).

Contrary to respondent's suggestion (see Br. in Opp. 1 n.1, 16), the label "Trust Fund" does not evidence any substantive difference between the Compensation Fund and most other federal funds. Like the Compensation Fund, many dedicated funds in the Treasury bear the formal label of "Trust Fund." See, *e.g.*, 26 U.S.C. Ch. 98, Subch. A ("Establishment of Trust Funds"). Like the Compensation Fund, such funds are generally an accounting and appropriations mechanism, and very few are actually held *in trust* for someone other than the United States.[2] Ordinary principles of sovereign im-

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[2] See, *e.g.*, *Flemming* v. *Nestor*, 363 U.S. 603, 608-611 (1960) (holding that an individual did not have a vested right to receive certain Social Security benefits from the Federal Old-Age and Survivors Insurance Trust Fund, 42 U.S.C. 401(a)); GAO, *Federal Trust and Other Earmarked Funds: Answers to Frequently Asked Questions* 7 (Jan. 2001) ("In the federal budget the meaning of the term 'trust' differs significantly from its private sector usage. * * * [I]n contrast to a private trust fund, the federal government does not have a fiduciary responsibility to the trust beneficiaries, and it can raise or lower future trust fund collections and payments or change the purposes for which the collections are used by changing existing laws. Moreover, the federal government has custody and control of the funds."), http://gao.gov/assets/210/200562.pdf; Off. of Mgmt. & Budget, *Analytical Perspectives: Budget of the U.S. Government* 133 (FY 2013) ("*Trust funds* account for the receipt and expenditure of monies by the Government for carrying out specific purposes and programs in accordance with the terms of a statute that

munity, including the canon that waivers of immunity are to be construed narrowly, therefore are fully applicable to the Vaccine Act.

2. An interpretation of the Vaccine Act that authorizes an award of attorneys' fees and costs on an untimely petition is disfavored because it would substantially depart from the common law

The extremely generous interpretation of the Vaccine Act's fee-shifting provision that respondent advances departs so far from background principles about who pays a litigant's attorneys' fees that it cannot be justified without a clearer statement than the Act can supply. "[S]tatutes which invade the common law . . . are to be read with a presumption favoring the retention of long-established and familiar principles, except when a statutory purpose to the contrary is evident." *United States* v. *Texas*, 507 U.S. 529, 534 (1993) (citations omitted) (brackets in original).

In certain respects, the Vaccine Act's remedial provisions do unambiguously deviate from prevailing legal practices. The very existence of a fee-shifting provision reflects a departure from the "American Rule," under which each party pays its own fees, *e.g.*, *Alyeska Pipeline Serv. Co.* v. *Wilderness Soc'y*, 421 U.S. 240, 247 (1975), and the Vaccine Act is especially unusual because it permits an award of fees when a claimant does not succeed on the merits. See Pet. App. 18a (Bryson, J., dissenting) ("[I]t is almost unknown in American practice for a statute to provide that the prevailing party will pay the losing party's attorneys' fees."). Thus, even as

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designates the fund as a trust fund (such as the Highway Trust Fund)."), http://www.whitehouse.gov/sites/default/files/omb/budget/fy2013/assets/spec.pdf.

construed by the government and by the dissenting members of the en banc court of appeals, Section 300aa-15(e)(1) exposes the United States to much more expansive potential fee liability than does the typical federal fee-shifting statute. That fact counsels particular hesitation before reading Section 300aa-15(e)(1) to authorize fee awards in additional situations that the provision does not clearly cover. See *id.* at 19a ("[B]ecause Congress departed from the governing principles applied in virtually every other federal fee-shifting statute, [the courts] should be cautious in interpreting the statutory mandate to extend beyond those cases in which fee-shifting was clearly intended.") (citing, *inter alia*, *Robert C. Herd & Co.* v. *Krawill Mach. Corp.*, 359 U.S. 297, 304-305 (1959)).

3. Consistent with this Court's approach to the interpretation of other fee-shifting provisions, the Vaccine Act's provision for attorneys' fees and costs should be read to avoid lengthy and complex fee litigation

This Court has cautioned that ambiguous language in federal fee-shifting provisions should be construed, when the text of the statute permits, to limit the length and complexity of fee litigation. In *Pierce*, the Court concluded that "the text of the statute permits, and sound judicial administration counsels, deferential review of a district court's decision regarding attorney's fees under the EAJA." 487 U.S. at 563. The Court based that conclusion in part on the assessment that a deferential approach "will implement [the Court's] view that a 'request for attorney's fees should not result in a second major litigation.'" *Ibid.* (quoting *Hensley*, 461 U.S. at 437).

That principle is directly applicable here. In a case where the special master has already conducted the

inquiry needed to reject a Vaccine Act claim on the merits, the further determination whether the petition was brought in good faith and with a reasonable basis can typically be made in an expeditious manner. By contrast, when a Vaccine Act petition has been dismissed as untimely, the determination required by 42 U.S.C. 300aa-15(e)(1) will often require fee litigation of a length and complexity that outstrips the underlying proceedings. See Pet. App. 20a-21a (Bryson, J., dissenting); pp. 20-25, *supra*. Construing Section 300aa-15(e)(1) in a manner that avoids such "shadow trial[s]" (Pet. App. 20a) is thus consistent with this Court's usual approach to the interpretation of federal fee-shifting provisions.

D. Other Reasons Given For The En Banc Majority's Holding Are Unpersuasive

The majority below gave several other reasons in support of its conclusion that attorneys' fees and costs may be awarded on an untimely Vaccine Act petition. None of those reasons withstands scrutiny.

1. The court of appeals believed that "[u]nless * * * [respondent's] filing was a 'petition filed'" for purposes of the fee-shifting provision, then "neither [the court of appeals] nor the [CFC] had jurisdiction over her appeal." Pet. App. 5a-6a. For two reasons, holding that a time-barred claim is not a "petition filed under section 300aa-11" would create no such "jurisdictional impasse." *Id.* at 14a & n.1 (Bryson, J., dissenting).

First, any court involved would have "jurisdiction to determine its jurisdiction." *Harmon* v. *Brucker*, 355 U.S. 579, 582 (1958) (per curiam). Second, 42 U.S.C. 300aa-12(a) alleviates the majority's specific concern by giving special masters broad jurisdiction "over proceedings to determine if a petitioner under [42 U.S.C. 300aa-

11] is entitled to compensation under the Program." That authority literally and logically includes the power to decide whether the claimant "is eligible under [42 U.S.C. 300aa-16] to file a petition for compensation." Pet. App. 14a-15a n.1 (Bryson, J., dissenting).

2. The court of appeals also expressed concern that, if the phrase "petition filed under section 300aa-11" is understood to exclude time-barred petitions, then the Secretary and special masters will be unable to perform various statutory obligations with respect to "petitions filed" under the Act "until a determination is made as to the timeliness of the petition." Pet. App. 6a-7a. That concern is unfounded because the obligations to which the court referred apply at the commencement of the action, when the claimant's allegations are taken as true and treated as sufficient to warrant further proceedings. For purposes of those requirements, a Vaccine Act petition can appropriately be treated as timely until the special master has definitively made a contrary determination. That is no different from ordinary litigation, in which "[a]t the pleading stage, general factual allegations * * * may suffice," even though "at the final stage, those facts (if controverted) must be supported adequately by the evidence." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (internal quotation marks and citations omitted).

3. Finally, the en banc majority believed its decision to be supported by prior Federal Circuit decisions (see, *e.g.*, *Shaw* v. *Secretary of HHS*, 609 F.3d 1372 (2010)) holding that "interim" fees may be awarded in Vaccine Act cases before the entry of judgment on the merits. The court stated: "Holding that attorneys' fees are only available where a petition has been subjected to a final adjudication on the merits is also inconsistent with the

recognized practice of awarding interim attorneys' fees, which by definition does not require a final adjudication on the merits." Pet. App. 10a-11a. For two reasons, prior Federal Circuit decisions allowing interim fees in Vaccine Act cases provide no sound basis for the decision below.

First, the Federal Circuit precedents allowing interim fees cannot be reconciled with the statutory text. The Vaccine Act authorizes the special master or court to award attorneys' fees either "[i]n awarding compensation on a petition filed under section 300aa-11" or, under certain circumstances, "[i]f the judgment of the [CFC] on such a petition does not award compensation." 42 U.S.C. 300aa-15(e)(1). Neither of those statutory conditions for a fee award—*i.e.*, an award of compensation, or a judgment that does not award compensation—can be satisfied until the claimant's entitlement to compensation for the underlying injury has been finally adjudicated. In light of the principles of sovereign immunity that inform the Vaccine Act's interpretation, see pp. 29-30, *supra*, there is no warrant for disbursing money from the Compensation Fund on an interim basis.

Second, even if interim fee awards were proper, that would be no reason to conclude that attorneys' fees can be awarded on untimely petitions. The Federal Circuit's initial opinion recognizing the possibility of "interim fees" in a Vaccine Act case rested in part on the court's perception that "[a] special master can often determine at an early stage of the proceedings whether a claim was brought in good faith and with a reasonable basis." *Avera* v. *Secretary of HHS*, 515 F.3d 1343, 1352 (2008). Thus, while the Federal Circuit has held that the Vaccine Act permits some fee awards before the entry of

judgment, see *Shaw*, 609 F.3d at 1374-1375, the special master must still acquire sufficient familiarity with the underlying facts to determine whether the "good faith" and "reasonable basis" requirements are satisfied. By the same token, the attorneys' fees provision's requirement of "a petition filed under section 300aa-11," 42 U.S.C. 300aa-15(e)(1), makes the availability of a Vaccine Act fee award—interim or otherwise—contingent on the timely submission of a claim. See p. 16, *supra*. Even if interim fee awards under the Vaccine Act were permissible in some circumstances, they could not properly be made without a finding that the petition was timely filed. The Federal Circuit's "interim fee" decisions accordingly provide no support for the proposition that fees may be awarded even after a petition has been dismissed as untimely.

CONCLUSION

The order of the court of appeals should be vacated, and the case remanded with instructions to deny respondent's motion for an award of attorneys' fees and costs.

Respectfully submitted.

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APPENDIX

1. 42 U.S.C. 300aa-10 provides:

Establishment of program

(a) Program established

There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

(b) Attorney's obligation

It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program[1] for such injury or death.

(c) Publicity

The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

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[1] So in original. Probably should be capitalized.

2. 42 U.S.C. 300aa-11 provides:

Petitions for compensation

(a) General rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) of this section with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa-12(d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death and—

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa-12 of this title on such petition, and

(II) such person elects under section 300aa-21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa-21(b) of this title or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa-16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988.

(4) If in a civil action brought against a vaccine administrator or manufacturer before October 1, 1988, damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

(5)(A) A plaintiff who on October 1, 1988, has pending a civil action for damages for a vaccine-related in-

jury or death may, at any time within 2 years after October 1, 1988, or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) of this section for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) of this section for such injury or death.

(6) If a person brings a civil action after November 15, 1988[1] for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) of this section for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine- related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) of this section for such injury or death.

(8) If on October 1, 1988, there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition un-

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[1] So in original. Probably should be followed by a comma.

der subsection (b) of this section for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court[2] is authorized to continue to receive, and forward, petitions for compensation for a vaccine- related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1) of this section, file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before October 1, 1988, if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

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[2] See Change of Name note below.

(2) Only one petition may be filed with respect to each administration of a vaccine.

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine man-

ufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was

caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information

A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule

The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

3. 42 U.S.C. 300aa-12 provides:

Court jurisdiction

(a) General rule

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa-11 of this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under section 300aa-11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa-11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) of this section shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 300aa-13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa-11(c)(1)(C)(ii) of this title.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Court of Federal Claims shall appoint the special masters, 1 of whom, by designation of the judges of the United States Court of Federal Claims, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Court of Federal Claims determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters on December 19, 1989, shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on December 19, 1989, shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Court of Federal Claims, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, title 5. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, title 5.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts[1] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrate judges shall be applied to the special masters.

(D) Coordinating with the United States Court of Federal Claims the use of services, equipment, personnel, information, and facilities of the United States Court of Federal Claims without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims

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[1] So in original. Probably should be a reference to the United States Court of Federal Claims.

on the number of petitions filed under section 300aa-11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) Special masters

(1) Following the receipt and filing of a petition under section 300aa-11 of this title, the clerk of the United States Court of Federal Claims shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of title 28. Such rules shall—

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall—

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e) of this section.

(B) In conducting a proceeding on a petition a special master—

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information—

(I) relating to the existence of the evidence described in section 300aa-13(a)(1)(B) of this title, or

(II) relating to any allegation in a petition with respect to the matters described in section 300aa-11(c)(1)(C)(ii) of this title, and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before October 1, 1988, the chief special master determines that the number of filings and resultant workload place an undue burden

on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information—

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) Action by United States Court of Federal Claims

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to

have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Court of Federal Claims no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action de-

scribed in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals

The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's[2] judgment with such court of appeals.

(g) Notice

If—

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) of this section (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section), or

(2) the United States Court of Federal Claims fails to enter a judgment under this section on a pe-

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[2] So in original. Probably should be a reference to the United States Court of Federal Claims.

tition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa-21(b) of this title or the petitioner may choose under section 300aa-21(b) of this title to have the petition remain before the special master or court, as the case may be.

4. 42 U.S.C. 300aa-13 provides:

Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition. The special master or court

may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) "Record" defined

For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa-11 of this title.

5. 42 U.S.C. 300aa-15 provides:

Compensation

(a) General rule

Compensation awarded under the Program to a petitioner under section 300aa-11 of this title for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

(i) result from the vaccine-related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related

travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 300aa-16(a)(2) of this title, actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

(b) Vaccines administered before effective date

Compensation awarded under the Program to a petitioner under section 300aa-11 of this title for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) of this section and may also include an amount, not to exceed a combined total of $30,000, for—

(1) lost earnings (as provided in paragraph (3) of subsection (a) of this section),

(2) pain and suffering (as provided in paragraph (4) of subsection (a) of this section), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e) of this section.[1]

(c) Residential and custodial care and service

The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) of this section shall be sufficient to enable the compensated person to remain living at home.

(d) Types of compensation prohibited

Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a) of this section, compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) Attorneys' fees

(1) In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover—

(A) reasonable attorneys' fees, and

(B) other costs,

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[1] So in original. Probably should be preceded by a closing parenthesis.

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before October 1, 1988, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and petitioned under section 300aa-11(a)(5) of this title to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before October 1, 1988, in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 300aa-11 of this title which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(f) Payment of compensation

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been

made, or has been deemed to have been made, under section 300aa-21(a) of this title to receive compensation.

(2) Compensation described ir subsection (a)(1)(A)(iii) of this section shall be paid from the date of the judgment of the United States Court of Federal Claims under section 300aa-12 of this title awarding the compensation. Such compensation may not be paid after an election under section 300aa-21(a) of this title to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C. 900 et seq.].

(4)(A) Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26 in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a

vaccine before October 1, 1988, the compensation shall be determined on the basis of the net present value of the elements of compensation and shall be paid from appropriations made available under subsection (j) of this section in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) of this section are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 300aa-21(a) of this title shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(g) Program not primarily liable

Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.]), or (2) by an entity which provides health services on a prepaid basis.

(h) Liability of health insurance carriers, prepaid health plans, and benefit providers

No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program, except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(i) Source of compensation

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death asso-

ciated with the administration of a vaccine before October 1, 1988, shall be made by the Secretary from appropriations under subsection (j) of this section.

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1988, shall be made from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(j) Authorization

For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, there are authorized to be appropriated to the Department of Health and Human Services $80,000,000 for fiscal year 1989, $80,000,000 for fiscal year 1990, $80,000,000 for fiscal year 1991, $80,000,000 for fiscal year 1992, $110,000,000 for fiscal year 1993, and $110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B) of this section. Amounts appropriated under this subsection shall remain available until expended.

6. 42 U.S.C. 300aa-16 provides:

Limitations of actions

(a) General rule

In the case of—

(1) a vaccine set forth in the Vaccine Injury Table which is administered before October 1, 1988, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 28 months after October 1, 1988, and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine,

(2) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition

may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

(b) Effect of revised table

If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa-11(b)(2) of this title, file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

(c) State limitations of actions

If a petition is filed under section 300aa-11 of this title for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed

and ending on the date (1) an election is made under section 300aa-21(a) of this title to file the civil action or (2) an election is made under section 300aa-21(b) of this title to withdraw the petition.

7. 42 U.S.C. 300aa-21 provides:

Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under section 300aa-12(f) of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa-11 of this title shall file with the clerk of the United States Court of Federal Claims—

> (1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or
>
> (2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection does not file the election

within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations on the bringing of civil actions for vaccine- related injuries or deaths associated with the administration of a vaccine after October 1, 1988, see section 300aa-11(a)(2) of this title.

(b) Continuance or withdrawal of petition

A petitioner under a petition filed under section 300aa-11 of this title may submit to the United States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition if—

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 300aa-12(d)(3)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa-12(d)(3)(C) or 300aa-12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title), or

(2) the court fails to enter a judgment under section 300aa-12 of this title on the petition within 420

days (excluding (i) any period of suspension under section 300aa-12(d)(3)(C) or 300aa-12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 300aa-12(g) of this title.

(c) Limitations of actions

A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 300aa-11 of this title shall, except as provided in section 300aa-16(c) of this title, be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

8. 26 U.S.C. 4131 provides:

Imposition of tax

(a) General rule

There is hereby imposed a tax on any taxable vaccine sold by the manufacturer, producer, or importer thereof.

(b) Amount of tax

(1) In general

The amount of the tax imposed by subsection (a) shall be 75 cents per dose of any taxable vaccine.

(2) Combinations of vaccines

If any taxable vaccine is described in more than 1 subparagraph of section 4132(a)(1), the amount of the tax imposed by subsection (a) on such vaccine shall be the sum of the amounts for the vaccines which are so included.

(c) Application of section

The tax imposed by this section shall apply—

(1) after December 31, 1987, and before January 1, 1993, and

(2) during periods after the date of the enactment of the Revenue Reconciliation Act of 1993.

9. 26 U.S.C. 9510 provides:

Vaccine Injury Compensation Trust Fund

(a) Creation of Trust Fund

There is established in the Treasury of the United States a trust fund to be known as the "Vaccine Injury Compensation Trust Fund", consisting of such amounts as may be appropriated or credited to such

Trust Fund as provided in this section or section 9602(b).

(b) Transfers to Trust Fund

(1) In general

There are hereby appropriated to the Vaccine Injury Compensation Trust Fund amounts equivalent to the net revenues received in the Treasury from the tax imposed by section 4131 (relating to tax on certain vaccines).

(2) Net revenues

For purposes of paragraph (1), the term "net revenues" means the amount estimated by the Secretary based on the excess of—

(A) the taxes received in the Treasury under section 4131 (relating to tax on certain vaccines), over

(B) the decrease in the tax imposed by chapter 1 resulting from the tax imposed by section 4131.

(3) Limitation on transfers to Vaccine Injury Compensation Trust Fund

No amount may be appropriated to the Vaccine Injury Compensation Trust Fund on and after the date of any expenditure from the Trust Fund which is not permitted by this section. The determination of whether an expenditure is so permitted shall be made without regard to—

(A) any provision of law which is not contained or referenced in this title or in a revenue Act, and

(B) whether such provision of law is a subsequently enacted provision or directly or indirectly seeks to waive the application of this paragraph.

c) Expenditures from Trust Fund

(1) In general

Amounts in the Vaccine Injury Compensation Trust Fund shall be available, as provided in appropriation Acts, only for—

(A) the payment of compensation under subtitle 2 of title XXI of the Public Health Service Act (as in effect on October 18, 2000) for vaccine related injury or death with respect to any vaccine—

(i) which is administered after September 30, 1988, and

(ii) which is a taxable vaccine (as defined in section 4132(a)(1)) at the time compensation is paid under such subtitle 2, or

(B) the payment of all expenses of administration (but not in excess of $9,500,000 for any fiscal year) incurred by the Federal Government in administering such subtitle.

(2) Transfers for certain repayments

(A) In general

The Secretary shall pay from time to time from the Vaccine Injury Compensation Trust Fund into the general fund of the Treasury amounts equivalent to amounts paid under section 4132(b) and section 6416 with respect to the taxes imposed by section 4131.

(B) Transfers based on estimates

Transfers under subparagraph (A) shall be made on the basis of estimates by the Secretary, and proper adjustments shall be made in the amounts subsequently transferred to the extent prior estimates were in excess of or less than the amounts required to be transferred.

(d) Liability of United States limited to amount in Trust Fund

(1) General rule

Any claim filed against the Vaccine Injury Compensation Trust Fund may be paid only out of such Trust Fund.

(2) Coordination with other provisions

Nothing in the National Childhood Vaccine Injury Act of 1986 (or in any amendment made by such Act) shall authorize the payment by the United States Government of any amount with respect

to any such claim out of any source other than the Vaccine Injury Compensation Trust Fund.

(3) Order in which unpaid claims to be paid

If at any time the Vaccine Injury Compensation Trust Fund has insufficient funds to pay all of the claims out of such Trust Fund at such time, such claims shall, to the extent permitted under paragraph (1) be paid in full in the order in which they are finally determined.

RESPONDENT'S BRIEF

RECORD AND BRIEFS

No. 12-236

FEB 4 - 2013

IN THE

Supreme Court of the United States

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

MELISSA CLOER,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT

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QUESTION PRESENTED

Section 300aa-11(a)(1) of the National Childhood Vaccine Injury Act of 1986 provides that "[a] proceeding for compensation under the [Act] for a vaccine-related injury or death shall be initiated by . . . the filing of a petition. . . ." Section 300aa-15(e)(1) provides that "on a petition filed under section 300aa–11 . . . [i]f the judgment . . . on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition . . . . [provided] that the petition was brought in good faith and with a reasonable basis."

The question presented is:

Whether section 15(e)(1)'s unqualified authorization of the payment of attorneys' fees incurred in connection with a petition that has been denied, so long as the petition was filed in good faith and with a reasonable basis, should be construed to contain a categorical exception prohibiting the payment of fees incurred on a petition that has been denied on statute of limitations grounds.

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INTRODUCTION

The Vaccine Act was designed to relieve those seeking compensation for vaccine-related injuries from the burdens of civil litigation, including the burden of paying for legal representation. To that end, the Act prohibits attorneys from receiving compensation from their clients for proceedings brought under the Act. At the same time, the Act was designed to ensure that those seeking compensation for their injuries were nonetheless able to retain qualified counsel to represent them. In order to serve this purpose, the Act's fee provision (section 300aa-15(e)(1)) not only mandates the payment of attorneys' fees incurred in connection with successful petitions, but also provides for the discretionary payment of attorneys' fees incurred in connection with petitions that award no compensation.

Section 15(e)(1) applies to any "petition filed under section 300aa-11," and it imposes only two conditions upon the discretionary payment of fees: the petition must be filed in good faith and with a reasonable basis.

Dr. Cloer's petition fits squarely within those requirements. At the time Dr. Cloer filed her petition, the case law supported the conclusion that it was timely. Then, three years later, the Chief Special Master ruled that the law had changed in a way that required the dismissal of Dr. Cloer's petition. But two years after that, a panel of the Federal Circuit Court reversed, holding that Dr. Cloer's petition was timely. And later still, the Federal Circuit Court sitting *en banc* affirmed the dismissal of Dr. Cloer's petition, but only after agreeing with Dr. Cloer that two significant lines of precedent interpreting the statute of

limitations should be overruled. In short, if ever there were a petition awarding no compensation to a claimant that was brought in good faith and with a reasonable basis, Dr. Cloer's petition is it.

Nevertheless, petitioner argues that the text of the Act establishes a categorical exception prohibiting the payment of fees incurred in connection with a petition that is denied as untimely, even if the petition was brought in good faith and with a reasonable basis. Petitioner's interpretation is not based upon the language of section 15(e)(1), nor is it based upon the language of section 300aa-11 — the provision expressly cross-referenced in section 15(e)(1). Rather, petitioner's interpretation is based upon the Act's statute of limitations set forth in section 300aa-16. Because section 16, employing language typical of limitations provisions, states that "no petition may be filed" after the limitations period has run, petitioner urges that a petition ultimately deemed untimely cannot constitute a "petition filed under section 300aa-11." Thus, the argument goes, an untimely petition is not eligible for an award of fees under section 15(e)(1) in any circumstance.

Petitioner's attempt to engraft the provisions of section 16 onto section 15(e)(1) fights with the most sensible, direct and plain reading of the statute. Section 15(e)(1) does not, as petitioner would have it, define what it means to "file" a petition by reference to section 16. Rather, section 15(e)(1) defines what it means to file a petition by reference to section 300aa-11, and neither section 15(e)(1) nor the filing provisions of section 11 say anything at all about the statute of limitations. As such, petitioner's interpretation substitutes a cross-reference to section 16 that Congress did not include in section 15(e)(1), for the explicit cross-

reference to section 11 that Congress did include. By any measure that is an unusual way to read a statute.

With only tenuous textual support, petitioner offers policy concerns as the primary justification for her interpretation of the Act. However, the concerns that petitioner relies upon are grossly exaggerated. Most notably, petitioner warns that it will be too complicated and time-consuming for special masters to determine whether a petition denied on limitations grounds was brought in good faith and with a reasonable basis, because they will not have wrestled with the underlying merits of such cases. The fact is, however, that special masters routinely make good faith/reasonable basis determinations about petitions denied on procedural grounds without a hearing, much less the sort of full blown "shadow trial" that petitioner warns will be necessary. Indeed, those determinations often can be made based solely upon the written documentation that must accompany the filing of a petition at the very outset. After all, the showing required to establish that a petition was brought in good faith and with a reasonable basis is far different from, and lower than, the showing required to establish the actual merits of a petition.

The Federal Circuit Court properly rejected petitioner's interpretation and ruled that the Act permits the payment of reasonable fees incurred in connection with unsuccessful petitions brought in good faith and with a reasonable basis, including reasonable fees incurred in connection with petitions that ultimately are denied as having been filed outside the limitations period. That ruling is correct and should be affirmed.

STATEMENT OF THE CASE

A. The National Childhood Vaccine Injury Act.

The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §300aa-10 *et seq.* ("Vaccine Act" or "Act") was designed to achieve two primary goals: to establish a superior alternative to the civil tort system for compensating individuals injured by vaccines; and to encourage a reliable supply of vaccines by reducing the burden of civil litigation that had driven a number of vaccine manufacturers to abandon the market. *Bruesewitz v. Wyeth LLC*, 131 S.Ct. 1068, 1073 (2011). Accordingly, the Act establishes a no-fault compensation program "designed to work faster and with greater ease than the civil tort system." *Ibid.* (quoting *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995)). "The *quid pro quo* for" the compensation program, "designed to stabilize the vaccine market, was the provision of significant tort liability protections for vaccine manufacturers." *Bruesewitz*, 131 S.Ct. at 1074. Although the Act does not preempt all civil actions for damages caused by vaccines, as a practical matter virtually all claims for vaccine-related injuries are resolved under the Act and without resort to the civil tort system. *Bruesewitz*, 131 S.Ct. at 1074 fn. 23.

The compensation program differs from the civil tort system in a number of important respects. The "[m]atters to be demonstrated . . . are relatively narrow and well-defined. Traditional discovery, cross-examination, pleadings, and trial are not allowed." H.R.Rep. No. 99–908 at 22 (1986) (the "1986 Report"). The Act directs the Court of Federal Claims to "provide for a less adversarial, expeditious, and informal proceeding

for the resolution of petitions," and to "include flexible and informal standards of admissibility of evidence." 42 U.S.C. §§300aa–12(d)(2)(A)–(B). For some petitions, causation is presumed, 42 U.S.C. §§300aa–11(c)(1), 300aa–13(a)(1)(A), (B), and under no circumstances are petitioners required to establish fault on the part of vaccine manufacturers. *Bruesewitz*, 131 S.Ct. at 1074.

The compensation program also differs from the civil tort system in the way it deals with the payment of attorneys' fees and costs.[1] Congress recognized that the burdens created by the tort system, including the obligation to pay attorneys' fees, could be a significant deterrent to seeking compensation for vaccine-related injuries. *See, e.g.*, 1986 Report at 6 ("Lawsuits and settlement negotiations can take months and even years to complete. Transaction costs — including attorneys' fees and court payments — are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met."). Congress addressed this problem by prohibiting attorneys from charging their clients fees for *any* services rendered in connection with a petition filed under the compensation program. 42 U.S.C. §300aa-15(e)(3).[2]

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1. For ease of reference, when we refer to the payment of attorneys' fees, we mean the payment of fees and costs.

2. As such, and despite petitioner's repeated references to section 15(e)(1) as a conventional "fee-shifting provision," *see, e.g.*, Brief For The Pet'r ("Br.") 6, 12, 13, 26, 33, the Act does not require one party to pay the fees that normally would be borne by the opposing party, as happens in a true fee-*shifting* case. The United States does not pay the fees that might otherwise be paid by claimants under the Act, because the Act prohibits attorneys from being paid fees by their clients. Indeed, the United States

While relieving petitioners of any obligation to compensate their attorneys, Congress nonetheless sought to ensure that its prohibition on private fee agreements would not discourage people from bringing claims for compensation under the Vaccine Act with the assistance of counsel, even where the success of those claims was not guaranteed. *See* 1986 Report at 22 ("the Committee does not intend that the limitation [on] fees . . . limit petitioners' ability to obtain qualified assistance and intends that the court make adequate provision for attorneys' time and that the court exercise its discretion to award fees in non-prevailing, good-faith claims"). *See also Saunders v. Secretary of HHS*, 25 F.3d 1031, 1035 (Fed.Cir.1994) (the fees and costs scheme of the Act is designed "to ensure that vaccine-injury claimants will have readily available a competent bar to prosecute their claims under the Act"). Thus, Congress not only mandated the payment of reasonable attorneys' fees incurred in connection with successful petitions, but also authorized the discretionary payment of fees incurred in connection with petitions resulting in no award of compensation:

> (1) In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover —

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does not "pay" the fees incurred by petitioners under the Act in any meaningful sense of the word at all. Rather, the United States *administers* the Vaccine Injury Compensation Trust Fund, which is the source of funds used to pay attorneys, and which is funded by a consumer-paid excise tax on vaccines. *See* 26 U.S.C. §9510; 26 U.S.C. §4131. The Fund's current balance is almost $3.5 billion. ftp://ftp.publicdebt.treas.gov/dfi/tfmb/dfivi1212.pdf.

> (A) reasonable attorneys' fees, and
>
> (B) other costs,
>
> incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

42 U.S.C. §300aa-15(e)(1).

In authorizing the payment of fees incurred in connection with unsuccessful petitions, Congress drew no distinctions or exceptions based upon the reasons for denial. The only conditions that apply to the discretionary payment of attorneys' fees are that petitions be brought in good faith and with a reasonable basis. In short, "[a]ttorney's fees are provided, not only for successful cases, but even for unsuccessful claims that are not frivolous." *Bruesewitz*, 131 S.Ct. at 1074.

B. Dr. Cloer's Petition.

Dr. Cloer received Hepatitis-B (Hep-B) vaccinations in September and November of 1996, and she received a third Hep-B vaccination in April of 1997. JA44. Shortly after her third vaccination Dr. Cloer experienced an electric shock

sensation in her spine and she lost sensation in her left arm and hand, but those symptoms soon resolved. JA44-5.

Additional problems arose in 1998 and Dr. Cloer then underwent testing by a neurologist (Dr. Meyer), including a magnetic resonance imaging (MRI) scan. JA45. The MRI indicated a number of *possible* diagnoses, including multiple sclerosis ("MS"). JA45, 52. It was not until November 26, 2003 that Dr. Cloer was given a diagnosis of MS, and even then it was only a "provisional" diagnosis suggested by her then-treating neurologist. JA46. In 2004, a physician conducting a comprehensive medical examination of Dr. Cloer noted that she "first beg[a]n to have some symptoms consistent with MS in 1997," although her "symptoms waxed and waned until the fall of 2003 when she beg[a]n to have manifestations of the full blown disease." Pet.App.160a.

Dr. Cloer first became aware of an association between MS and the Hep-B vaccine when she read an editorial and a prospective French study in the September 2004 issue of *Neurology*. JA47. Roughly one year later, Dr. Cloer filed a claim for compensation under the Vaccine Act alleging that her Hep-B vaccinations had caused her MS or significantly aggravated her latent MS condition. Pet.App.155a-156a. Dr. Meyer's unrebutted testimony before the special master established that before 2004, a member of the medical community at large would not have recognized or believed that Dr. Cloer's MS, which itself was first provisionally diagnosed in 2003, was the result of the Hep-B vaccine administered back in 1996 and 1997. Pet.App.102a.

C. The Proceedings Below.

Dr. Cloer filed her petition for compensation on September 16, 2005. Pet.App.155a. In response to petitioner's motion to dismiss, Dr. Cloer argued, *inter alia*, that her petition was timely because it was filed within 36 months of the time her MS first manifested itself, pursuant to the holding of *Setnes v. Secretary of HHS*, 57 Fed.Cl. 175 (2003). Pet.App. 165a-67a. In the alternative, Dr. Cloer argued that the Vaccine Act's statute of limitations should be equitably tolled given that she had no objective reason to know that she had suffered a vaccine-related injury before 2004 (when the medical profession first recognized a link between the Hep-B vaccine and MS). Pet.App.173a-74a.

In a May 15, 2008 ruling, the Chief Special Master acknowledged that the "issue presented in this case evolved with the development of the case law," noting that the arguments "took place within the context of the *Setnes* ruling . . . [that] unquestionably presented much reasonable room for disagreement and debate." Pet.App.167a. But the special master concluded that the ruling of *Setnes* was implicitly overruled in *Markovich v. Secretary of HHS*, 477 F.3d 1353 (Fed.Cir.2007) and that *Markovich* required that Dr. Cloer's petition be dismissed as untimely. Pet.App.165a & fn.9, 173a-74a. The Chief Special Master rejected Dr. Cloer's equitable tolling argument based upon circuit precedent holding that the Act's statute of limitations is not subject to tolling under any circumstances. Pet.App.176a. The United States Court of Federal Claims affirmed. Pet.App.154a.

By a 2-1 vote, the United States Court of Appeals for the Federal Circuit reversed. The court agreed with Dr. Cloer's interpretation of *Markovich* and held that her 2005 petition was timely under that interpretation because the undisputed evidence established that the medical community at large did not recognize a link between the Hep-B vaccine and MS until 2004. Pet.App.96a, 102a.

In granting petitioner's request for rehearing *en banc*, the court directed the parties to submit supplemental briefs on a number of specific issues, including whether "*Brice v. Secretary of [HHS]*, 240 F.3d 1367 (Fed.Cir.2001), [should] be overruled to permit equitable tolling." Pet. App.86a. Resolution of that question turned in large part on whether the Vaccine Act's statute of limitations is a jurisdictional provision. *See Holland v. Florida*, 130 S.Ct. 2549, 2560 (2010) (this Court has "previously made clear that a nonjurisdictional federal statute of limitations is normally subject to a rebuttable presumption in *favor* of equitable tolling") (internal citations and quotations omitted; emphasis in original). And resolution of that question in turn implicated the Federal Circuit's precedent on the subject of attorneys' fee awards. That precedent held that because the Vaccine Act's statute of limitations is jurisdictional, a court has no jurisdiction over untimely petitions and thus, no jurisdiction to award attorneys' fees incurred in connection with an untimely petition. *See Brice v. Secretary of HHS*, 358 F.3d 865 (Fed.Cir.2004) ("*Brice II*") (relying upon *Martin ex rel. Martin v. Secretary of HHS*, 62 F.3d 1403 (Fed.Cir.1995)).

By a vote of 8-4, the Federal Circuit ruled that the Vaccine Act's statute of limitations is not jurisdictional, that it is subject to equitable tolling, and that the

jurisdictional/attorneys' fee rule established in *Brice II* should be overruled — all positions that had been advanced by Dr. Cloer. *Cloer v. Secretary of HHS*, 654 F.3d 1322 (Fed.Cir.2011) (*en banc*) ("*Cloer I*"); Pet.App.57a-65a, 58a at fn.9; Fed.Cir.Doc.No. 46, 23-38, 29 at fn.9.[3] However, the grounds for equitable tolling identified by the court encompassed only "fraud or duress," which did not apply to Dr. Cloer, who had relied upon the broader standard for equitable tolling established in *Pace v. DiGuglielmo*, 544 U.S. 408, 418 (2005). Pet.App.65a-66a; Fed.Cir.Doc. No. 46, 38-41. Consequently, the majority ruled that Dr. Cloer's petition was untimely.

Dr. Cloer then moved for an award of attorneys' fees and costs incurred on appeal and in recognition of the fact that *Cloer I* had overruled the holding of *Brice II*. By a vote of 7-6, the Federal Circuit again agreed with Dr. Cloer, ruling that the untimeliness of her petition was not a bar to the payment of attorneys' fees. *Cloer v. Secretary of HHS*, 675 F.3d 1358 (Fed.Cir.2012) (*en banc*); Pet.App.1a-21a. The court articulated several different grounds for its ruling, including the following.

First, relying upon the plain language of the Act, the court noted that "[i]t is beyond dispute that Congress

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3. The four dissenting judges expressed no disagreement with the majority's holding that the statute of limitations is a nonjurisdictional provision or with the majority's decision to overrule *Brice II*. Rather, the dissenting judges would have ruled that Dr. Cloer's petition was timely on grounds that the Vaccine Act's statute of limitations contains a "discovery rule" whereby the limitations period begins to run only after a petitioner has, or should have, knowledge of both her injury and its cause. Pet. App.75a-83a.

intended attorneys' fees to be awarded in cases brought in good faith and where there was reasonable basis for the claim underlying the petition, even where the petitioner does not prevail." Pet.App.9a. Because the plain language of section 15(e)(1) authorizes the payment of fees "incurred in any proceedings" on a petition, with the only qualification being that the petition was brought in good faith and with a reasonable basis, the court concluded that the reason for the denial of Dr. Cloer's petition was immaterial. Pet.App.5a-6a. In short, the court concluded that "[t]he good faith and reasonable basis requirements apply to the claim for which the petition was brought; this applies to the entire claim, including timeliness issues." Pet.App.9a.

The court also concluded that "[t]he plain language of the statute indicates that Congress chose not to tie the right to attorneys' fees to compliance with [the statute of limitations set forth in] §300aa–16" because "Section 300aa–15(e) does not reference §300aa–16 . . . [but only] refers to 'a petition filed under section 300aa–11' . . . [and] the plain language of §300aa–11(a)(1) [does not] require that a petition be timely filed in accordance with §300aa–16." Pet.App.6a. "By contrast," the court observed, section "300aa–11(a)(2)(A), which refers to civil actions brought in state or federal court, does require the filing of a petition 'in accordance with section 300aa–16.'" Pet.App.6a. Thus, the court held that the "absence of an analogous reference to §300aa–16 in the attorneys' fees provision suggests that Congress did not intend to require compliance with §300aa–16 as a prerequisite for the recovery of attorneys' fees." Pet.App.6a.

Finally, the court concluded that an award of fees was particularly appropriate in this case because Dr.

Cloer's petition had "inspired a shift in Vaccine Act jurisprudence" and because the Secretary "does not dispute the reasonableness of Dr. Cloer's underlying claim or allege that it was not brought in good faith." Pet.App.9a.

The dissenting judges would have reached a different result for five reasons. First, the dissent argued that under *Brice II* and *Martin* no petition could be filed past the limitations period, that fees are only available for petitions "filed" under the Act, and that therefore no fees could be awarded on an untimely petition. Pet.App.13a-14a. Second, the dissent urged that section 15(e)(1)'s authorization for the payment of fees where "the judgment" awards no compensation, refers only to a judgment on the merits and not to a judgment dismissing a petition as untimely. Pet. App.15a. The basis for this construction was the fact that a separate provision of the Act refers to a "judgment" in the context of a judgment on the merits, so the dissent concluded that Congress must have intended a similar meaning for the word "judgment" in section 15(e)(1). Pet. App.15a. Third, while asserting that the legislative history "is silent as to the reasons for the Act's highly unusual attorney fee provision," Pet.App.16a-17a, the dissent nevertheless relied upon that history in speculating that "Congress could well have concluded that it did not make sense to provide attorneys' fees" incurred in connection with claims denied on limitations grounds. Pet.App.18a.

Fourth, the dissent stated that, because the Act's fee provision was unusual in that it "plainly allows losing parties to obtain a fee award," the court should "be cautious in interpreting the statutory mandate to extend beyond those cases in which fee-shifting was clearly intended." Pet.App.19a. And fifth, the final paragraph of the dissenting opinion warned that permitting an award

of attorneys' fees in cases where a petition is denied as untimely will necessitate "a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding." Pet.App.20a-21a. Because of the burden such proceedings would impose upon special masters, the dissent concluded that "it seem[ed] unlikely that Congress envisioned such a scheme." *Ibid.*

Petitioner does not defend or rely upon the dissent's first rationale (based upon the overruled cases of *Brice II* and *Martin*, Pet.App.9a, 14a) or its third rationale (that the silent legislative history might support an inference about Congress's intent). Nor does petitioner defend or rely upon the dissent's second rationale — that the meaning of the word "judgment" includes only final judgments on the merits and not final judgments entered on limitations grounds. *See* Fed.R.Civ.P. 54(a) ("[j]udgment" as used in these rules includes a decree and any order from which an appeal lies"). Petitioner does press the fourth point (that the fee provision should be narrowly construed). And it is the dissent's final point, with its isolated reference to "shadow trials," which forms the central policy justification for petitioner's interpretation of the Act.

SUMMARY OF THE ARGUMENT

Section 15(e)(1) applies to "petition[s] filed under section 300aa-11," and it authorizes the payment of fees incurred in connection with petitions that award no compensation to a claimant with only two qualifications: the petition must have been brought in good faith and with a reasonable basis. Section 15(e)(1) does not contain an exception for petitions denied on limitations grounds

(or denied for any other reason). Moreover, neither section 15(e)(1) nor the filing provisions of section 11 says anything at all about a petition having to comply with the statute of limitations set forth in section 16. Yet it is section 16's use of the phrase "no petition may be filed" that petitioner relies upon in support of her argument that an untimely petition is not a petition that can be considered "filed" for purposes of section 15(e)(1). As such, petitioner's interpretation of section 15(e)(1) seeks to substitute a requirement that Congress did not impose (compliance with section 16) for a requirement that Congress did impose (compliance with section 11).

When Congress intended provisions of the Act to require both the filing of a petition and the filing of a petition in accordance with section 16, it did so expressly. It did not do so with the Act's fee provision. Because Congress knew how to require that a filing comply with the limitations provision when that is what it intended, Congress's failure to impose that requirement in section 15(e)(1) must be regarded as a deliberate choice, and one to be honored rather than ignored.

Indeed, there are several other "filing" provisions of the Act, in addition to section 15(e)(1), that make clear that when Congress referred only to the "filing" of a petition, it was not referring only to petitions filed in accordance with the statute of limitations. Thus, petitioner eventually concedes that untimely petitions can in fact be "filed" for many different purposes under the Act, just not, it is claimed, for the purpose petitioner opposes in this case.

Moreover, petitioner's interpretation assumes that the statute of limitations' use of the phrase "no petition

may be filed" amounts to a flat prohibition upon the filing of an untimely petition. That assumption might make sense if the statute of limitations were a jurisdictional bar. This Court has been emphatic, however, in holding that ordinary statutes of limitations like that contained in the Vaccine Act are not jurisdictional. Thus, a fatal flaw with petitioner's interpretation is that, although petitioner never acknowledges the fact, her interpretation of section 15(e)(1) is premised upon the faulty assumption that the statute of limitations operates as if it were a jurisdictional bar.

Petitioner ultimately relies upon policy concerns, more so than the statute's text, as the principal justification for her interpretation of section 15(e)(1), arguing that permitting the payment of fees incurred in connection with petitions that are denied as untimely will be "wasteful, painful, and complex." None of these policy arguments furnish support for the interpretation petitioner proposes.

Petitioner argues that fee awards in cases like this will be "wasteful" because they provide no monetary benefit to the petitioners themselves. But that is true of fee awards denied on *any* grounds, not just those denied on limitations grounds. That did not stop Congress from explicitly authorizing the payment of fees incurred in connection with denied petitions, however. Thus, petitioner's policy arguments about wastefulness do not support her interpretation of the Act, they represent a disagreement with the judgment that Congress has made.

Petitioner argues that to award fees incurred on petitions that have been denied will be "painful" because such proceedings will expose a petitioner's medical

records, require that she be examined by an expert, and might even require her family members to testify at a trial. But the Act requires that all petitions be accompanied by a wide range of medical records at the time of filing. Thus, it is not a request for fees that exposes a petitioner's medical records; it is the act of seeking compensation itself that does so. What is more, the written documentation accompanying the petition is often the only information a special master needs to determine whether a petition was brought in good faith and with a reasonable basis – no expert examination is required, nor is testimony by family members.

Determining whether a petition that has been denied on limitations grounds was brought in good faith and with a reasonable basis does not require a complicated "shadow trial." The inquiry is fundamentally different than that required to resolve the merits of a petition. Special masters routinely make good faith/reasonable basis determinations about petitions that have been denied on procedural grounds where there has been little or no examination of the underlying merits, and they do so based solely upon the documentation that must accompany the filing of a petition, and without a hearing. It is a determination special masters routinely make with relative ease.

None of the general canons of statutory construction invoked by petitioner can justify the interpretation she proposes. On its face, section 15(e)(1) does not create a categorical exception prohibiting the payment of fees incurred in prosecuting petitions that are denied as untimely. As such, the canon that waivers of sovereign immunity should be narrowly construed is irrelevant (to

the extent it applies, even in theory, to legislation like the Vaccine Act). The risk here lies not in expanding the waiver beyond that which Congress provided, but in narrowing that express waiver by implying an exception to it that Congress did not intend.

Petitioner notes that section 15(e)(1) is a generous fee provision, and argues from this that it should therefore be narrowly construed. Congress unquestionably did intend section 15(e)(1) to be generous. But there is no canon of statutory construction that can justify interpreting the Act in a way that makes it less generous than Congress intended.

ARGUMENT

A. The Act's Authorization For Payment Of Attorneys' Fees Incurred On Petitions That Are Denied Contains No Exception For Petitions Denied On Limitations Grounds.

1. Nothing In The Language Or Structure Of Section 15(e)(1) Permitting The Payment Of Fees On Petitions That Are Denied, If Brought In Good Faith And With A Reasonable Basis, Carves Out An Exception For Petitions Denied As Untimely.

Section 15(e)(1) permits the payment of attorneys' fees incurred in connection with petitions that award no compensation to a claimant with only two qualifications: a petition that is denied must be brought in good faith and with a reasonable basis. The statute provides, in relevant part, as follows:

> [O]n a petition filed under section 300aa-11 of this title . . . [i]f the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs *incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.*

42 U.S.C. §300aa-15(e)(1) (emphasis added).

Congress plainly intended to permit compensation for attorneys' fees incurred in connection with petitions that are denied. The only conditions that Congress placed upon such awards are that the unsuccessful petition be brought in good faith and with a reasonable basis. *See Bruesewitz*, 131 S.Ct. at 4 ("[a]ttorney's fees are provided, not only for successful cases, but even for unsuccessful claims that are not frivolous"). Furthermore, section 15(e)(1) expressly permits the payment of fees "incurred in any proceeding," without excluding proceedings commenced by the filing of petitions ultimately denied as untimely. Section 15(e)(1) permits the payment of fees incurred on "a petition [that] does not award compensation," without excluding petitions that are denied on limitations grounds (or denied for any other reason). In sum, section 15(e)(1) authorizes the payment of fees incurred in any proceedings pertaining to petitions that are denied, regardless of the reason for that denial.

Nonetheless, petitioner argues that a categorical exception prohibiting the payment of fees incurred in connection with a petition denied as untimely should be read into section 15(e)(1). Petitioner's argument ignores each and every word that is used in section 15(e)(1) with the exception of one: the section's authorization for the payment of fees incurred on a petition that has been "filed." Seizing upon that word, and tying it to the statute of limitations' use of the phrase "no petition may be filed" after the limitations period has run, petitioner argues that an untimely petition is not a petition that is "filed" within the meaning of section 15(e)(1). However, there is no reason to think that when Congress authorized and specifically referred to the payment of fees incurred in connection with a "petition filed under section 300aa-11," Congress actually meant that its authorization extended only to a "petition filed in accordance with the statute of limitations set forth in section 300aa-16." But that is exactly how petitioner reads the Act — replacing a cross-reference that Congress used with a cross-reference that Congress did not use.

The word "filed" appears in section 15(e)(1) as part of the phrase, "a petition filed under section 300aa-11." When considered in context, section 15(e)(1) uses the word "filed" to refer to the requirements of section 300aa-11. Thus, while petitioner ignores the provisions of section 300aa-11, that section actually holds the key to determining what constitutes a petition that is "filed" for purposes of section 15(e)(1).

The filing requirements applicable to all petitions brought under the Act are set forth in subsection 300aa-11(a)(1). That subsection provides that a proceeding for compensation under the Act is initiated by the "filing of

a petition containing the matter prescribed by subsection (c) of this section . . . with the United States Court of Federal Claims." Thus, a filing under section 11(a)(1) requires two things: (1) a petition containing the matter prescribed by section 300aa-11(c); and (2), a petition that is filed with the United States Court of Federal Claims.

Importantly, none of the "matter prescribed by subsection [300aa-11](c)" has anything to do with the Act's statute of limitations.[4] Subsection 11(c) requires, in relevant part, that every petition contain "an affidavit, and supporting documentation" establishing that the injured person received a vaccine. §300aa-11(c)(1)(A). In addition, subsection 11(c) requires that a petition specify whether the injured person sustained an injury set forth in the Vaccine Injury Table within the time period set forth in the Table, sustained an injury that is not set forth in the Table, or sustained an injury set forth in the Table but outside the time period identified in the Table. §300aa-11(c)(1)(C)(i) & (ii). Nothing in subsection 11(c) requires any documentation, or calls for the making of any allegations, about the timeliness of a petition for purpose of the statute of limitations. Thus, a petition is not required to substantiate or allege that the first symptom or manifestation of onset of the injury in question occurred within 36 months of the petition's filing.[5]

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4. The Act's statute of limitations provides, in relevant part, that a petition must be brought within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such [vaccine] injury." 42 U.S.C. §300aa-16(a)(2).

5. The fact that timeliness might be inferred from some petitions alleging a Table injury (by virtue of the requirement that such petitions allege that the onset/manifestation occurred within the particular time period set forth in the Table), is a coincidence

Similarly, there is nothing about subsection 11(c)'s requirement that a petition be "filed" with the Court of Federal Claims that suggests Congress intended such a filing to be in accordance with the statute of limitations. Rather, a pleading "is 'filed,' as that term is commonly understood, when it is delivered to, and accepted by, the appropriate court officer for placement into the official record." *Artuz v. Bennett*, 531 U.S. 4, 8 (2000) (internal citations omitted).[6]

In sum, section 15(e)(1)'s authorization for a court to pay fees incurred in connection with a "petition filed under section 300aa-11" does not require that the filing comply with the statute of limitations set forth in section 16. Consequently, there is no textual support for petitioner's contention that by requiring that a petition be "filed under section 300aa-11," Congress actually intended (albeit implicitly) to require that a petition be "filed in accordance with section 300aa-16."

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of no consequence here. Such an inference could not be drawn from the overwhelming majority of petitions filed under the Act, since the pleading requirements for non-Table injuries do not require allegations about the timing of an injury. *Cf. Stevens v. Secretary of HHS*, 2001 WL 387418 at *8 (Fed.Cl.Spec.Mstr. March 30, 2001) (anecdotal evidence indicates that "90% of cases" are premised upon non-Table injuries and "practice has shown that virtually all of the cases proceed as causation-in-fact disputes"). Nor could such an inference be drawn even in Table cases where the injury period and running of the statute of limitations overlap.

6. By contrast, a pleading "is '*properly* filed' when its delivery and acceptance are in compliance with the applicable laws and rules governing filings . . . [such as those prescribing] the form of the document, the time limits upon its delivery, the court and office in which it must be lodged, and the requisite filing fee." *Id.* at 8 (footnote omitted; emphasis in original).

Moreover, the Vaccine Act, "like every Act of Congress, should not be read as a series of unrelated and isolated provisions." *Gustafson v. Alloyd Co.*, 513 U.S. 561, 570 (1995). That, however, is exactly how petitioner is reading the Act. And by focusing exclusively upon a single word — "filed" — petitioner loses sight of the overall structure of section 15(e)(1).

The first paragraph of section 15(e)(1) identifies its subject (awards of compensation on a petition filed under section 300aa-11) and contains the provision's directive (that any award of compensation include an amount to cover certain items). Subparagraphs (A) and (B) specify what those items are (attorneys' fees and costs) and the provision ends by specifying that eligible fees and costs are those incurred "in any proceedings." Congress used the same structure with respect to the discretionary payment of fees incurred on "such petitions" that result in no award of compensation, with only one exception: it added requirements that "the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought."

If, as petitioner contends, Congress intended discretionary fee awards to be conditional upon compliance with the statute of limitations, "[i]t would have been much easier (and much more natural)," *Bruesewitz*, 131 S. Ct. at 1076 (2011), to have included that requirement at the end of section 15(e)(1), where the other conditions applicable to such awards are identified. That is, Congress could have provided that fees may be paid "if the special master or court determines that the petition *was filed in accordance with section 300aa-16* and was brought in good faith and there was a reasonable basis for the claim for which the petition was brought." Thus, the best reading of the Act

is that it fails to mention compliance with the statute of limitations "by deliberate choice, not inadvertence." *Bruesewitz*, 131 S.Ct. at 1076 (quoting *Barnhart* v. *Peabody Coal Co.*, 537 U. S. 149, 168 (2003)).

At a minimum, if Congress intended section 15(e)(1)'s use of the word "filed" in the introductory paragraph to require compliance with section 300aa-16, it would have expressly included that limitation when referring to such a filing, just as it included that limitation in other provisions of the Act. *See, infra*, Argument A.2. That is, Congress could have provided that the fee provision applies when "awarding compensation on a petition filed under section 300aa-11 and *in accordance with section 300aa-16*."

But Congress did neither of those things. Rather, it simply provided the authority to award fees and costs on petitions "filed under section 300aa-11," without specifying that such authority extends only to petitions that are filed under section 11 *and* filed in accordance with section 16.

2. When Congress Intended That A Petition Be "Filed" And Filed In Accordance With The Statute Of Limitations, Congress Expressly Stated That Intention.

Any doubt about the significance of Congress's decision not to explicitly reference section 16 in section 15(e)(1) or in section 11(a)(1), is conclusively resolved by Congress's decision to do so in section 300aa-11(a)(2)(A).[7]

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7. As noted above, section 11(a)(1) establishes the filing requirements applicable to all petitions brought under the Act. Section 11(a)(2)(A), by contrast, is an exhaustion provision governing the post-petition filing of civil actions that are not

Unlike section 11(a)(1), section 11(a)(2)(A) expressly requires both that a petition be "filed" *and* be filed in accordance with the statute of limitations:

> No person may bring a civil action for damages . . . in a State or Federal court for damages arising from a vaccine-related injury or death . . . *unless a petition has been filed, in accordance with section 300aa–16 of this title.*

42 U.S.C. §300aa-11(a)(2)(A) (emphasis added).

Congress thus plainly knew how to require that a "filed" petition be filed "in accordance with section 16" and chose to do so for purposes of section 11(a)(2)(A). Congress did not impose that requirement in section 11(a)(1). The only reasonable conclusion to be drawn from this different treatment is that Congress did not intend to require compliance with the statute of limitations as a prerequisite to the payment of fees incurred on a "petition filed under section 11," provided the petition was filed in good faith and with a reasonable basis. If Congress had intended to require compliance with the statute of limitations, it would have so stated. *See, e.g., Bates v. United States*, 522 U.S. 23, 29-30 (1997) ("where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion") (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).

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otherwise preempted by the Act. A post-petition civil action can only be brought after the judgment on a petition has been rejected by the claimant or if a judgment has not entered in a timely fashion. *See* 42 U.S.C. §§300aa-21(a) & (b).

Recognizing that the distinction between 11(a)(1) and 11(a)(2)(A) presents a formidable barrier to her interpretation of the Act, petitioner offers a number of arguments about why the distinction should be ignored. First, petitioner argues that section 15(e)(1)'s reference to a "petition filed under section 300aa-11," and section 16's statement that "no petition may be filed" beyond the limitations period, "obviates the need for other cross-references to the limitations provision." Br. 17. If that were true, it would apply equally to section 11(a)(2)(A), which likewise concerns a "petition filed" under the Act, but specifically requires that such a petition be filed "in accordance with section 300aa–16." Consequently, petitioner's explanation renders section 11(a)(2)(A)'s explicit reference to section 16 mere surplusage. *See, e.g., TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (noting "cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant") (internal quotations omitted); *United States v. Menasche*, 348 U.S. 528, 538-539 (1955) ("[i]t is our duty 'to give effect, if possible, to every clause and word of a statute'") (quoting *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883)).[8]

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8. Petitioner says that its argument on this point is supported by *Astrue v. Capato*, 132 S.Ct. 2021 (2012), Br.17, but *Astrue* is easily distinguished. In *Astrue*, the Court ruled that one statutory provision defining the term "child" did not need to explicitly cross-reference a second provision also defining the term "child," in order for the first provision to be qualified by the definition contained in the second. *Id.* at 2031. But the Court did not reach that conclusion in the face of a third provision defining the term "child" and expressly cross-referencing the definition set forth in the second provision. As such, the Court was not confronted with, and certainly did not endorse, the superfluity problem that petitioner's argument suffers from in this case.

Second, petitioner argues that if every provision of the Act that is subject to the statute of limitations must "expressly reference the limitations provision" that would mean the "failure to comply with the limitations provision would not even bar recovery under the Compensation Program itself because 42 U.S.C. 300aa-13 ('Determination of eligibility and compensation') does not expressly cross-reference the limitations provision." Br. 18. This argument rests upon a faulty premise.

Dr. Cloer does not contend, and the Federal Circuit did not hold, that in order to be impacted by the statute of limitations (for example, to constitute a defense to a petition for compensation), a provision must explicitly cross-reference section 16. Dr. Cloer's point is more limited: she argues merely that one provision of section 300aa-11 requires the "filing of a petition" without regard to the issue of timeliness, whereas the very next provision of the very same section requires both the filing of a petition *and* that such filing be "in accordance with section 300aa-16." Congress is presumed to mean something different when it uses different language, particularly when the difference supports a perfectly sensible distinction: Congress intended one provision to require compliance with the statute of limitations, but not the other.

Third, petitioner offers that Congress had two "sound reasons . . . to include the express cross-reference in Section 300aa-11(a)(2)(A)" because that provision is central to Congress's intent to stabilize the vaccine market by reducing civil litigation. Br. 18. The first reason identified by petitioner is that section 11(a)(2)(A) "has preemptive effect" and thus, the cross-reference to the Act's statute

of limitations was included to clearly state Congress's intention to preempt state law. Br. 19. The argument is wrong.

The Vaccine Act's preemption provisions are set forth in section 300aa-22. Section 11(a)(2)(A) is not a preemption provision. Rather, it establishes an exhaustion requirement that must be met before a plaintiff can pursue claims that are *not preempted* under the Act in state or federal court. Moreover, and even if one assumes that this exhaustion requirement can be described accurately as having some "preemptive effect," it is the exhaustion requirement itself that has that effect, *to wit*, that a claim first must be brought under the Vaccine Act. It is not the additional requirement that such a claim be brought in a timely manner that has any preemptive effect. Thus, the rule that Congress should clearly state its intention to preempt state law is not a rule that explains why Congress expressly would have required that a petition be filed in accordance with the statute of limitations in section 11(a)(2)(A), but not included the same requirement in section 11(a)(1), if it intended both provision to require compliance with section 16.

The second reason petitioner suggests Congress might have required compliance with the statute of limitations in section 11(a)(2)(A) but not in section 11(a)(1), is that section 11(a)(2)(A) is addressed to state and federal courts of general jurisdiction, rather than to "expert special masters." Br. 19. Petitioner argues that "[t]he convenience and clarity of the express cross-reference . . . makes it unnecessary for such generalist courts to familiarize themselves with the intricacies of the Vaccine Act, when they are called upon only to apply a straightforward rule

about timely exhaustion of remedies under the Act." Br. 19. The argument has no merit.

If section 11(a)(2)(A) did not require that a filing comply with the statute of limitations, the provision would still, and only, require courts of general jurisdiction to make a "straightforward" determination about exhaustion of remedies under the Act without familiarizing themselves with the (unidentified) "intricacies of the Vaccine Act." The same is true of section 11(a)(2)(A) as written. The only difference is that as written, Congress made clear that a civil litigant must not only exhaust her remedies under the Act, she must do so in accordance with the statute of limitations. As such, the express cross-reference contained in 11(a)(2)(A) does not relieve state and federal courts from wrestling with the intricacies of the Vaccine Act, because they would not be required to do so even in the absence of that cross-reference.

Fourth, and finally, petitioner argues that any "unexplained discrepancy between Section 300aa-11(a)(1) and Section 300aa-11(a)(2)(A)" is of no consequence because "Congress often employs language 'out of an abundance of caution' and 'to remove any doubt' on an issue." Br. 19. There is, of course, no "unexplained discrepancy" with section 11 if one concludes, simply and logically, that by requiring compliance with the statute of limitations in one provision, but not in the other, Congress intended exactly that.[9]

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9. In any event, if Congress was drafting section 11 in an abundance of caution and with an eye towards removing any doubt about the statute of limitations' applicability, it would have required compliance with the limitations period in section 11(a)(1) explicitly if that is what it intended, just as it did in section 11(a)(2)(A).

3. Many Provisions Of The Act Establish That An Untimely Petition Can In Fact Be "Filed," As Petitioner Eventually Concedes.

The Vaccine Act contains a number of provisions, in addition to section 15(e)(1), that apply to petitions that have been "filed" without reference to the statute of limitations. It is both illogical and impractical to conclude that any of those provisions apply only to petitions that have been filed *and* filed in accordance with section 16. Accordingly, the presence of all of those provisions supports the conclusion that a petition is "filed" under the Act irrespective of the statute of limitations, and that same conclusion should apply to section 15(e)(1). *See, e.g., Ratzlaf v. United States*, 510 U.S. 135, 143 (1994) ("[a] term appearing in several places in a statutory text is generally read the same way each time it appears").

The *en banc* majority discussed several of these "filing" provisions in detail, Pet.App.6a-7a, so we focus upon only one. Section 300aa-12(a)(2) requires that, "[w]ithin 30 days after the Secretary receives service of any petition filed under section 300aa-11 of this title the Secretary shall publish notice of such petition in the Federal Register." It would defy common sense to think that by requiring the Secretary to publish notice of any "petition filed under section 300aa-11" — *the identical phrase used in section 15(e)(1)* — Congress intended the Secretary to make a unilateral determination about a petition's timeliness before deciding whether to publish notice of the petition. And not surprisingly, in this very case, the Secretary published notification that Dr. Cloer's petition had been "filed under section 300aa-11." *See* 70 F.R. 73011, 73014, ¶131.

Thus, it is evident that when Congress referred to a "petition filed under section 300aa-11" in the publication provision, it could not have meant only a petition filed in accordance with the statute of limitations. And in fact, petitioner concedes as much by acknowledging that this statutory requirement (as well as the others discussed by the *en banc* majority) is to be discharged without regard to a petition's timeliness. Br. 35 (insisting that it is "unfounded" to think that "the Secretary and special masters will be unable to perform various statutory obligations with respect to 'petitions filed' under the Act 'until a determination is made as to the timeliness of the petition'").

The question, therefore, is how an untimely petition can be considered "a petition filed under section 300aa-11" for purposes of publishing notification, while that same petition is considered not to have been "filed under section 300aa-11" for purposes of section 15(e)(1), by virtue of its untimeliness. Petitioner's only explanation for this contradiction is to say that at the "commencement of the action, when the claimant's allegations are taken as true and treated as sufficient to warrant further proceedings . . . a Vaccine Act petition can appropriately be treated as [illegible]ely until the special master has definitively made a contrary determination." Br. 35. There are two basic problems with this explanation.

First, the Vaccine Act does not require a petition to include any allegations about compliance with the statute of limitations. *See* 42 U.S.C. §300aa-11(c). *See also, supra*, p. 22 & fn.5. Thus, petitioner is wrong in stating that at "the commencement of the action," a petition includes allegations that, if "taken as true," would be sufficient to assume that the petition complies with the statute of limitations.

Second, it is one thing to say that the legal status of a pleading can change over time -- that a petition can be assumed to be timely but later proven to be untimely, or that a cause of action can be sufficiently pled but later proved to be unfounded. It is something entirely different to say that Congress would have used the identical language to describe things having a different legal status — that Congress would have referred to a "petition filed under Section 300aa-11" to describe a petition without regard to its timeliness, while at the same time referring to a "petition filed under Section 300aa-11" to mean only a petition that is filed "in accordance with the statute of limitations."

In the end, petitioner's interpretation is reduced to the position that an untimely petition is not a petition that can be "filed under section 300aa-11," even though petitioner acknowledges that an untimely petition can in fact be "filed under section 300aa-11."

B. Petitioner's Interpretation Of The Act Rests Upon The Erroneous Assumption That The Act's Statute Of Limitations Functions As A Jurisdictional Bar To The Filing Of An Untimely Petition.

In *Cloer I*, the *en banc* court ruled that the Act's statute of limitations was not a jurisdictional provision. Pet.App.9a-10a, 58a fn.9. Not a single member of the court disagreed with that conclusion, and petitioner did not seek review of that holding in this Court. Petitioner has declined to make an explicit argument that the statute of limitations is jurisdictional in the case now before the Court.

Despite this, petitioner's interpretation of the phrase "no petition may be filed" — and by extension, petitioner's interpretation of section 15(e)(1) itself — rests upon the unstated assumption that the Act's statute of limitations functions as a jurisdictional bar. There is no other way to explain how an untimely petition that unquestionably has been "filed" as a matter of *fact*, can be regarded as having never been filed as a matter of *law*, which is the upshot of petitioner's interpretation of section 15(e)(1). In other words, petitioner's interpretation of section 15(e)(1) rests upon the premise that the statute of limitations should have the effect of a jurisdictional bar, without establishing (or even arguing) that the statute of limitations is a jurisdictional provision. If, however, the statute of limitations is not jurisdictional, and if the phrase "no petition may be filed" does not operate to bar or effectively nullify a petition that otherwise has been filed, that alone is reason to reject petitioner's interpretation of section 15(e)(1).

1. This Court's Precedent Establishes That The Statute Of Limitations Is Not A Jurisdictional Provision.

This Court has "repeatedly held that filing deadlines ordinarily are not jurisdictional" but are instead "quintessential claim-processing rules." *Sebelius v. Auburn Regional Med. Ctr.*, 2013 WL 215485 at *6 (U.S. Jan. 22, 2013) (internal quotations omitted). And "[t]o ward off profligate use of the term 'jurisdiction,' [this Court has] adopted a readily administrable bright line for determining whether to classify a statutory limitation as jurisdictional . . . inquir[ing] whether Congress has clearly state[d] that the rule is jurisdictional; absent such

a clear statement, we have cautioned, courts should treat the restriction as nonjurisdictional in character." *Id.* at *7 (internal quotations and citations omitted).

The general rule that statutes of limitations are not jurisdictional applies regardless of "how[] emphatic" the time prescription is stated, *Arbaugh v. Y & H Corp.*, 546 U. S. 500, 510 (2006). *See also Henderson v. Shinseki*, 131 S.Ct. 1197, 1204-05 (2011) (time prescription applicable to filing before Article I tribunal was not jurisdictional, even though it was "cast in mandatory language [because the Court has] rejected the notion that all mandatory prescriptions, however emphatic, are . . . properly typed jurisdictional") (internal quotations omitted); *Reed Elsevier, Inc. v. Muchnick*, 130 S.Ct. 1237, 1244 (2010) (time prescription that "no civil action for infringement of the copyright in any United States work shall be instituted" is a claim-processing rule, not a jurisdictional limitation); *Kontrick v. Ryan*, 540 U.S. 443, 448, 454 (2004) (deadline providing that objections "shall be filed no later than 60 days after the first date set for the meeting of creditors" is not a jurisdictional limitation). *Cf. Beach v. Ocwen Fed. Bank*, 523 U.S. 410, 416 (1998) ("most statutes of limitation provide either that 'all actions ... shall be brought within' or 'no action ... shall be brought more than' so many years") (quoting Note, Developments in the Law: Statutes of Limitations, 63 Harv. L.Rev. 1177, 1179 (1950)).

This Court also has "repeatedly stated that the enactment of time-limitation periods . . . without further elaboration, produces defenses that are nonjurisdictional and thus subject to waiver and forfeiture." *Holland v. Florida*, 130 S.Ct. 2549, 2560 (2010) (internal citations and quotations omitted). *See also Wood v. Milyard*, 132 S.Ct. 1826, 1832 (2012) ("[o]rdinarily in civil litigation,

a statutory time limitation is forfeited if not raised in a defendant's answer or in an amendment thereto"); *Semtek Int'l Inc. v. Lockheed Martin Corp.*, 531 US 497, 504 (2001) ("the traditional rule is that expiration of the applicable statute of limitations merely bars the remedy").

Petitioner's interpretation of the Act, however, assumes that the statute of limitations does something very different than provide an affirmative defense subject to waiver and forfeiture. Petitioner interprets the phrase "no petition may be filed" to mean that an untimely petition like Dr. Cloer's — although filed with the court, published in the Federal Register, and litigated for years — is to be considered a petition that was never "filed" in the first place. That interpretation makes sense (if at all) only if a determination of untimeliness divests a court of jurisdiction over a petition, or if an untimeliness ruling somehow operates to retroactively nullify the filing of a petition. But petitioner has never cited any authority in support of a nullification theory, and any claim that the Act's statute of limitations is jurisdictional would have to be rejected in light of this Court's precedent (and for the reasons identified by the Federal Circuit in *Cloer I* and by Dr. Cloer below, Fed.Cir.Doc. 46, 23-38).[10]

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10. Petitioner's interpretation of the phrase "no petition may be filed" also overlooks the fact that this Court has "made clear that a nonjurisdictional federal statute of limitations is normally subject to a rebuttable presumption in *favor* of equitable tolling." *Holland*, 130 S.Ct. at 2560 (internal citations and quotations omitted; emphasis in original). And, of course, the Federal Circuit sitting *en banc* ruled that the Vaccine Act's statute of limitations is subject to equitable tolling. As such, petitioner also is incorrect in assuming that no untimely petition can be considered to have been "filed" under the Act.

2. Various Provisions Of The Vaccine Act Also Establish That The Statute Of Limitations Is Not A Jurisdictional Provision.

Petitioner's interpretation of the phrase "no petition may be filed" also conflicts with the provisions of the Vaccine Act. The Act vests the Court of Federal Claims and its special masters with "jurisdiction *over proceedings* to determine if a petitioner under section 300aa–11 of this title is entitled to compensation under the [Vaccine] Program." 42 U.S.C. §300aa–12(a) (emphasis added). A "proceeding for compensation" under section 300aa-11(a)(1) is commenced by the "filing of a petition." Thus, if an untimely petition is not a petition that has been "filed" within the meaning of the Act, as petitioner argues, then such a petition cannot commence a "proceeding." And if an untimely petition cannot commence a proceeding, that would lead, as the federal circuit noted, to the conclusion that "neither we [the Federal Circuit] nor the Court of Federal Claims had jurisdiction over Dr. Cloer's appeal." Pet.App.5a-5b.

Petitioner's primary response to this observation is to argue that her interpretation of the phrase "no petition may be filed" creates no "jurisdictional impasse" because a court always has jurisdiction to determine its own jurisdiction. Br. 34. That argument misses the point. The federal circuit rejected petitioner's interpretation because if the Act's language is applied consistently, that interpretation would lead to the conclusion that a court has no jurisdiction over an untimely petition. The problem with that conclusion is not that a court would lack jurisdiction to determine its own jurisdiction. The problem is that the *en banc* court in *Cloer I* expressly ruled that the Act's

statute of limitations is not a jurisdictional provision and to hold otherwise would be inconsistent with this Court's precedent.

Moreover, had Congress intended the statute of limitations to operate in the way that petitioner proposes, Congress could have provided that "no petition *shall be deemed* to have been filed" after the limitations period has run, rather than using the conventional statute of limitations language that it did use, which historically has been treated as a nonjurisdictional and waiveable defense. *See, e.g., Midlantic Nat'l Bank v. New Jersey Dep't of Envt'l Protection*, 474 U.S. 494, 501 (1986) ("[t]he normal rule of statutory construction is that if Congress intends for legislation to change the interpretation of a judicially created concept, it makes that intent specific") (quoting *Edmonds v. Compagnie Generale Transatlantique*, 443 U.S. 256, 266-67 (1979)).

C. The Purposes Underlying The Vaccine Act Do Not Support Construing The Act To Exclude Fee Awards On Petitions Filed In Good Faith And With A Reasonable Basis, But Denied On Limitations Grounds.

Given the problems and inconsistencies with petitioner's interpretation of section 15(e)(1), it is not entirely surprising that petitioner relies heavily upon policy concerns as the justification for that interpretation. However, those policy concerns furnish no better basis for petitioner's position than do her textual arguments.

Petitioner's central argument is that permitting an award of attorneys' fees in cases that are denied on

limitations grounds is fundamentally inconsistent with the Act's design to work more efficiently than the civil tort system, because such awards will require "'a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding.'" Br. 22 (quoting Pet. App.20a). Petitioner warns: "Such a collateral proceeding would be wasteful, painful, and complex — the antithesis of the system that Congress designed to work faster and with greater ease than the civil tort system." Br. 22. (internal quotations omitted). These concerns are unfounded.

Before turning to petitioner's policy arguments, it is important to understand exactly what is involved in determining whether a petition was brought in good faith and with a reasonable basis. "Good faith" is a subjective standard and it is presumptively satisfied in the absence of evidence to the contrary. *See, e.g., Austin v. Secretary of HHS*, 2012 WL 592891 at *4 (Fed.Cl.Spec. Mstr. Jan. 24, 2012) (collecting cases). The "reasonable basis" requirement is an objective standard. *McKellar v. Secretary of HHS*, 101 Fed.Cl. 297, 305 (2011). It is satisfied not by establishing that the allegations in a petition are true, but by showing that there is some basis for those allegations. Thus, a special master ruling upon a request for fees will never be confronted with the more difficult question, for example, of whether petitioner's causation expert is right, or has offered a more compelling opinion than that offered by a competing expert. *Cf. Heath v. Secretary of HHS*, 2011 WL 4433646 at *3 (Fed.Cl.Spec. Mstr. Aug. 25, 2011) (petition denied for failure to prove causation, but fees awarded because, while the court did "not find this [causation] expert's opinions persuasive . . .

they support a finding that petitioner had a good faith belief in vaccine causation of [the child's] injuries").

Given these standards, the good faith/reasonable basis determination as applied to this case implicates none of petitioner's stated concerns. Having succeeded before the three judge panel on her limitations argument and having succeeded, at least to some extent, before the *en banc* court, there can be no question that Dr. Cloer had a good faith and reasonable basis for filing her petition, as the Federal Circuit specifically recognized. Pet.App.5a ("Dr. Cloer asserted a reasonable limitations argument"); 9a ("her appeal inspired a shift in vaccine jurisprudence"). And as the Federal Circuit also correctly observed, "the government does not dispute the reasonableness of Dr. Cloer's underlying claim or allege that it was not brought in good faith." Pet.App.9a. *See also* Pet.App.157a (the Chief Special Master noting that "[t]he facts presented in this matter are uncontested").

And regarding petitions denied on limitations grounds generally, there is no merit to the assertion that the good faith/reasonable basis determinations will be "wasteful, painful, [or] complex." Br. 22. Petitioner says these determinations will be "wasteful" because such awards "cannot possibly result in compensation for injured persons" and "can produce no tangible benefit for claimants themselves, only for their lawyers." Br. 20, 23. Congress, of course, saw it otherwise when it authorized the payment of fees on unsuccessful petitions as a way of ensuring that future and prospective claimants would be able to obtain legal representation under the Act. That is to say, petitioner's observation holds true in every case involving the payment of fees incurred in connection with

petitions that award no compensation to the claimant, and not just in those denied on limitations grounds. The same is true of petitioner's claim that it would be "wasteful" to permit the payment of attorneys' fees incurred in fee proceedings themselves. Br. 22-3. Petitioner's policy concerns about wastefulness provide no support for her interpretation of the Act, because they amount to nothing more than a disagreement with the policies that Congress adopted.

Paying fees in cases like this would be "painful," petitioner argues, because "the attorneys' fee inquiry would call on the claimant to further expose her medical records (and perhaps herself) to examination by a new round of experts, and face a trial of sorts." Br. 23. Indeed, petitioner goes so far as to claim that even "the claimant's family members . . . could be called upon to participate in fee proceedings." *Ibid.* These concerns are not valid.

It is not a request for the payment of fees that will "expose [a claimant's] medical records," it is the very fact of filing a petition that does so. That is because the Act requires that all petitions be accompanied, *at the time of filing*, by a vast assortment of medical records relating to the alleged vaccine injury (or an identification of the records that are missing together with an explanation of why they are missing). 42 U.S.C. §300aa-11(c)(2), (3) (all petitions "shall contain," among other things, "maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and

medication records), if applicable, a death certificate, and if applicable, autopsy results.").[11]

Nor is there any reason that expert examinations, a "trial of sorts," or testimony from family members would be required to make the good faith/reasonable basis determination. Special masters are authorized to decide *the merits* of cases on the "basis of written filings without an evidentiary record." *Vaccine Rule* 8(d). It follows *a fortiori* that a special master can rely upon the written filings when deciding, not whether a petitioner should receive compensation, but whether she was justified in bringing her petition to begin with. *See, e.g., Rydzewski v. Secretary of HHS*, 2008 WL 382930 at *5 (Fed.Cl.Spec. Mstr. Jan. 29, 2008) (characterizing as "untenable" petitioner's argument that a hearing on fees should have been held to determine whether there was a reasonable basis for her petition, in part, on grounds that petitioner "was not entitled to such a hearing as a matter of right . . . [but only] at the discretion of the special master").

For many of the same reasons, petitioner's primary concern about the "complexity" of the good faith/reasonable basis determination is vastly overstated. Because the Vaccine Act requires that petitions be substantiated from the outset, the good faith/ reasonable basis determination

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11. For this same reason, petitioner also is mistaken in claiming that where a petition has been denied on limitations grounds, "the special master will have amassed no record . . . that can be used to determine whether the claim was brought in 'good faith' and had a 'reasonable basis' on the merits." Br.21. As Dr. Cloer's case itself demonstrates, special masters will have extensive medical records, affidavits and other information before them concerning all filed petitions, including those denied on limitations grounds. *See generally* JA40-69, Pet.App.157a-164a.

is quite straightforward. *See, e.g., Lamar v. Secretary of HHS*, 2008 WL 3845157 at *2-3 (Fed.Cl.Spec. Mstr. July 30, 2008) ("The authority to pay unsuccessful litigants and the requirements of good faith and reasonable basis should be considered against the backdrop of the Vaccine Act's requirements for filing a *substantiated* petition. . . . When a complete and substantiated petition is filed, determining whether the petition is filed in good faith and upon a reasonable basis can be made at the outset of the case.") (emphasis in original).

Thus, special masters routinely look no further than the written submissions that accompany the filing of a petition that has been denied when determining whether there was a good faith and reasonable basis justifying the payment of fees. *See, e.g., Brown v. Secretary of HHS*, 2005 WL 1026713 at *2 (Fed.Cl.Spec.Mstr. April 26, 2005) ("a reasonable basis could be proved in any number of ways including via a single medical record or a medical record plus a narrative from the petitioner").

Sometimes that determination is made after some limited examination of the underlying merits of a petition. *See, e.g., Scheuman v. Secretary of HHS*, 2010 WL 3421956 at *4 (Fed.Cl.Spec.Mstr Aug. 11, 2010) (petition denied based upon written record; finding of good faith/ reasonable basis based solely upon evidence adduced in different cases, but involving the same vaccine and alleged injury); *Wedzicha v. Secretary of HHS*, 1989 WL 250125 (Fed.Cl.Spec.Mstr. Sept. 22, 1989) (cursory hearing revealed that petitioner had no evidence of causation; petition voluntarily withdrawn and fees awarded based upon finding of good faith/reasonable basis).

Other times the good faith/reasonable basis determination follows only a procedural ruling "on threshold grounds without any meaningful analysis of the merits," Br.21, and without the special master having "studied and resolved the pertinent merits issues." Br.20. *See, e.g., Wells v. Secretary of HHS*, 28 Fed.Cl. 647, 664 (Fed.Cl.1993) (petition denied with no substantive proceedings on the merits; affirming special master's award of fees entered on finding of good faith and reasonable basis); *Hamrick v. Secretary of HHS*, 2007 WL 4793152 (Fed.Cl.Spec.Mstr. Jan. 9, 2008) (petition withdrawn following claimant's death, with no proceedings conducted on the merits, determined to have been brought in good faith and with a reasonable basis); *Rydzewski*, 2008 WL 382930 (petition denied with no substantive proceedings; payment of fees denied because there was no reasonable basis for petition where petition alleged but failed to substantiate that claimant had received the vaccine in question); *Brown v. Secretary of HHS*, 2005 WL 1026713 (Fed.Cl.Spec.Mstr. Mar. 11, 2005) (petition denied with no substantive proceedings on the merits; fees denied because there was no reasonable basis where, among other things, no medical documentation of vaccine was submitted); *Di Roma v. Secretary of HHS*, 1993 WL 496981 (Fed.Cl.Spec.Mstr. Nov. 18, 1993) (petition denied with no substantive proceedings; fees denied because proper investigation would have shown no reasonable basis for petitioner's claim).

Regardless of whether there has been some limited examination of the facts or no substantive examination at all, the good faith/reasonable basis determination does not require special masters to conduct any type of hearing, much less a complex trial. None of the representative cases cited above suggest that any substantive hearing

was required — *either on the merits or on the question of payment of fees* — in order to resolve the good faith/reasonable basis issue. This makes perfect sense, because the question of whether a petition was brought in good faith and with a reasonable basis for purposes of section 15(e)(1) requires far less than a special master having "resolved the pertinent merits issues," as petitioner contends. Br.20.

Moreover, and unlike the cases discussed above, in order to determine that a petition has been brought beyond the limitations period, a special master will have to evaluate the underlying facts, at least in cases where the limitations issue is a close one. Timeliness determinations require an evaluation of when the "first symptom" or "manifestation of onset" or "significant aggravation" of a vaccine-related injury occurred, a determination of what that injury is, and a determination about the nature of its symptoms, manifestations or aggravations. 42 U.S.C. §300aa-16(a)(2). Thus, and as this case amply demonstrates, special masters are likely to have a much deeper understanding of the underlying merits of a case denied on limitations grounds (where a valid argument about timeliness has been made) than they will have in a case denied for any number of other reasons, making the good faith/reasonable basis determination that much easier. Accordingly, petitioner's assertion that "fee proceedings on untimely petitions are likely to be more elaborate and time-consuming than on petitions where judgment has been entered on the merits," Br.26, has it exactly backwards.[12]

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12. In this same vein, petitioner cites *Smith v. Secretary of HHS*, 2006 WL 5610517 (Fed.Cl. July 21, 2006), as a case that "aptly illustrates the problems that would arise during shadow trials." Br.24. What *Smith* really illustrates is the fact that some

In sum, the determinations that must be made in order to pay attorneys' fees under section 15(e)(1) can be made without the feared "shadow trial." Special masters routinely make such determinations without difficulty and without struggling with any of the systemic problems that underpin petitioner's policy argument. To the extent there is even the slightest merit to petitioner's policy concerns, '[t]he government's policy arguments respecting the administrative burden on the [Court of Federal Claims] . . . are properly addressed to Congress, not to this Court." *Kosak v. United States*, 465 U.S. 848, 869 (1984) (Stevens, J., dissenting) (discussing the Federal Tort Claims Act) (internal quotations omitted).

Finally, petitioner warns that the Federal Circuit's decision "is likely to increase the number of untimely Vaccine Act petitions" which will "impede the prompt resolution of meritorious claims for much-needed compensation." Br.26-7. Petitioner acknowledges that this concern is entirely speculative (Br.26), and for good reason. Due in no small part to the persistence of Dr. Cloer, much of the doctrinal uncertainty surrounding the Act's statute of limitations has now been resolved: the "reasonable debate" about the meaning of *Setnes* has been settled; the contours of *Markovich* have been examined by a three-judge panel and established by the *en banc* court; the question of whether the Act's statute of limitations encompasses a traditional discovery rule has been answered; and the questions of whether equitable tolling is available, and under what circumstances, have been resolved. *See, supra*, pp.10-15 (The Proceedings Below).

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timeliness determinations require a relatively careful examination of the underlying facts, which then renders the subsequent fee determination a simple matter.

Consequently, there is every reason to think that timeliness determinations will pose little difficulty in the overwhelming majority of potential cases, and there will be little room to argue that an untimely petition nevertheless was filed with a "reasonable basis." On the other hand, creating a categorical exception prohibiting the payment of fees incurred on petitions that involve a genuine statute of limitations issue will discourage petitioners from seeking compensation under the Act, contrary to Congress's intent. *See* Pet.App.11a (*en banc* majority noting that categorical exception "would discourage potential Vaccine Act petitioners . . . [who] will likely be reluctant to bring claims under the Vaccine Act for fear of significant financial risk even when strong arguments exist to challenge the applicability of the statute of limitations").

To the extent petitioner's concern is that a flood of time-barred petitions will be filed by lawyers hoping to recover their fees, that is unfounded. Any obviously time-barred petitions will be summarily denied, and any subsequent request for fees will be dispatched just as quickly. That, coupled with the ethical obligations of attorneys, should be enough to dissuade the filing of time-barred petitions that raise no legitimate issue about the applicability of the statute of limitations.

With respect to the Federal Circuit's decision to recognize the availability of equitable tolling in *Cloer I*, given the exceedingly narrow grounds of fraud or duress that the court identified as the basis for tolling (not to mention the actual result reached in Dr. Cloer's case), there is no reason to think that any more than a very small number of claimants will bring otherwise untimely petitions by pinning their hopes upon that doctrine.

In all events, it is petitioner who is advancing these policy arguments as the justification for her interpretation of the Act. It is, therefore, incumbent upon the petitioner to offer at least some factual or empirical basis for thinking that these policy concerns are valid. But petitioner has offered none.

D. None Of The General Canons Of Statutory Construction Discussed By Petitioner Justify The Creation Of A Categorical Exception To The Act's Fee Provision That Congress Did Not Adopt.

Petitioner argues that her interpretation of the Act is supported by three canons of statutory construction. But if there is any canon of statutory construction that is obviously applicable to the Act and the question before this Court, it is "the well-accepted principle that remedial legislation . . . is to be given a liberal construction consistent with the Act's overriding purpose." *United States v. An Article of Drug*, 394 U.S. 784, 798 (1969). *See also Atchison, Topeka and Santa Fe Ry. Co. v. Buell*, 480 U.S. 557, 561-62 (1987) (same). One clear Congressional purpose underlying the Act was to create incentives for attorneys — who can receive no remuneration from their clients — to represent claimants even when the success of the petitioner's claim is not assured. Congress did so by providing for the payment of fees on petitions that are denied, without regard to the reason why a petition has been denied. Section 15(e)(1) should be construed broadly (if such a broad construction is even required) so as to effectuate that purpose.

Nonetheless, petitioner argues that her interpretation of the Act is supported by the notion that "the scope of the Vaccine Act's waiver of sovereign immunity —

including the United States' liability to pay respondent's attorneys' fees and costs — should be strictly construed." Br. 29. The strict construction of waivers of sovereign immunity is but one canon of statutory construction, however. It is not controlling where, as here, traditional canons (like those discussed in Part A above) resolve any purported statutory ambiguity. *See Richlin Sec. Service Co. v. Chertoff*, 553 U.S. 571, 589 (2008) ("The sovereign immunity canon is just that — a canon of construction. It is a tool for interpreting the law, and we have never held that it displaces the other traditional tools of statutory construction."). *Cf. United States v. Brown*, 333 U.S. 18, 25-6 (1948) ("The canon in favor of strict construction is not an inexorable command to override common sense and evident statutory purpose. It does not require magnified emphasis upon a single ambiguous word in order to give it a meaning contradictory to the fair import of the whole remaining language.") (discussing canon as applied to penal legislation).

Moreover, section 15(e)(1) is an express waiver of sovereign immunity for purposes of the payment of attorneys' fees in general, and the payment of such fees incurred in connection with petitions awarding no compensation to a claimant in particular. The question here is whether that unqualified waiver of immunity should be construed to contain a categorical exception for fees incurred in connection with petitions denied on limitations grounds. Consequently, this case is less about avoiding an interpretation that would extend the waiver beyond what Congress intended than it is about avoiding the opposite problem: "in construing the statute [the Court] must be careful not to 'assume the authority to narrow the waiver [of sovereign immunity] that Congress intended,'

or construe the waiver 'unduly restrictively.'" *Bowen v. City of New York*, 476 U.S. 467, 479 (1986) (quoting *United States v. Kubrick*, 444 U.S. 111, 118 (1979); *Block v. North Dakota*, 461 U.S. 273, 287 (1983)).

On a more fundamental level, it is doubtful that the Vaccine Act implicates sovereign immunity considerations in the first place. This Court has long recognized that traditional rules about sovereign immunity are "inapplicable where the Government has cast off the cloak of sovereignty and assumed the status of a private commercial enterprise." *Library of Congress v. Shaw*, 478 U.S. 310, 317 fn.5 (1986) (citing *Standard Oil Co. v. United States*, 267 U.S. 76, 79 (1925)). That principle applies squarely to legislative schemes which mimic private insurance. *See Standard Oil Co.*, 267 U.S. at 79 ("[w]hen the United States went into the insurance business, issued policies in familiar form and provided that in case of disagreement it might be sued, it must be assumed to have accepted the ordinary incidents of suits in such business").

The Vaccine Act was intended by Congress to establish a consumer-funded insurance system that would replace traditional civil tort actions against manufacturers of covered vaccines. *See* Joint Committee on Taxation, *Issues Arising in the Determination of an Appropriate Funding Source for the National Childhood Vaccine Injury Program* at 2 (March 4, 1987) (explaining that the Vaccine Act "substitutes *a Federal insurance system* for the existing State-law tort and private insurance system," and characterizing "[t]he excise tax on the vaccine [as] essentially an *insurance premium* to cover compensation for potential vaccine-related injuries") (emphasis added).

Such compensation funds are "treated as a trust fund," they have "the same characteristics as any insurance carrier," and thus, "[i]t is common that pursuant to such statutes the fund . . . will not be entitled to sovereign immunities that would not be afforded to private insurance carriers." Lee R. Russ & Thomas F. Sewall, *Couch on Insurance* §10:12 (3d ed.1995). *Compare Sandia Oil. Co. v. Beckton*, 889 F.2d 258, 263-64 (10th Cir.1989) (holding that FEMA's flood insurance program was not a "commercial enterprise" rendering concerns about sovereign immunity inapplicable because "[t]he flood insurance program was intended from the beginning to be, not a commercial enterprise, but rather a *subsidized* insurance program . . . designed to accomplish important national *goals at some cost to the national treasury*") (emphasis added).

Petitioner responds to this argument with a lengthy discussion about the legal and practical mechanisms employed by the federal government to impose taxes and handle the funds collected as a result. Br.30-31. But none of that changes the fact that the Vaccine Act was intended to substitute a form of unsubsidized federal insurance for the civil tort system, and none of it changes the fact that the judicially-created canon of statutory construction applicable to traditional waivers of sovereign immunity does not apply in such a context.

Next, petitioner argues that the "extremely generous interpretation of the Vaccine Act's fee-shifting provision that respondent advances departs so far from the background principles about who pays a litigant's attorneys' fees that it cannot be justified without a clearer statement than the Act can supply." Br.32 (invoking canon that caution should be used when interpreting statutes

that are in derogation of the common law). But Congress was unmistakably clear in providing for the payment of attorneys' fees incurred in connection with petitions that are denied. Petitioner's real complaint is not with an "extremely generous interpretation" of the Act advocated by Dr. Cloer, but with an "extremely generous" law that Congress enacted. *See* Br. 33 (complaining that even on the dissent's reading, section 15(e) "exposes the United States to much more expansive potential fee liability than does the typical federal fee-shifting statute").

Third, and finally, petitioner argues "that ambiguous language in federal fee-shifting provisions should be construed . . . to limit the length and complexity of fee litigation" so that "a request for attorney's fees [will] not result in a second major litigation." Br. 33 (internal quotations omitted). As already explained, however, the fee determination regarding petitions denied as untimely often will be less lengthy and complex than that relating to petitions denied for other reasons, the litigation of which has not been demonstrated by petitioner to be either lengthy or complex. Moreover, *Pierce v. Underwood*, 487 U.S. 552, 563 (1988), the only authority cited in support of petitioner's argument, is irrelevant. *Pierce* adopted a deferential standard of *appellate* review of district court fee determinations in order to avoid a "second major litigation" on fee issues. *Id.* at 563. *Pierce* did not adopt a general rule that fees should be denied categorically in some cases because doing so will avoid fee litigation altogether.

None of the general canons of construction relied upon by petitioner fit in the context of a statutory provision that is not a true "fee-shifting" provision to begin with, nor

in the context of a fee payment provision that Congress made unusually (and uniquely) broad.

CONCLUSION

The Federal Circuit's decision should be affirmed and the case remanded for further proceedings.

Respectfully submitted,

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REPLY BRIEF

No. 12-236

In the Supreme Court of the United States

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

MELISSA CLOER

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

Until the decision below, the Federal Circuit had never endorsed an award of attorneys' fees and costs on an untimely petition under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), 42 U.S.C. 300aa-1 *et seq.* To the contrary, the Federal Circuit had held that fee awards were unavailable in that circumstance. *Brice* v. *Secretary of HHS*, 358 F.3d 865, 868-869 (2004) (*Brice II*); cf. *Martin* v. *Secretary of HHS*, 62 F.3d 1403, 1405-1407 (Fed. Cir. 1995). Under that precedent, the Compensation Program that Congress "designed to work faster and with greater ease than the civil tort system," *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011) (quoting *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995)), has functioned largely as Congress intended, with attorneys providing the representation Congress sought to attract through the promise of the Act's generous fee-shifting provision, 42 U.S.C.

300aa-15(e)(1). Respondent's position is incorrect as a textual matter, would undermine the simplicity and efficiency the Act is structured to foster, and runs contrary to multiple canons of statutory construction. The court of appeals should be instructed to deny respondent's motion for attorneys' fees and costs.

A. A Straightforward Reading Of The Vaccine Act's Text Favors The Government's Interpretation, While Respondent's Textual Analysis Is Ad Hoc And Unpersuasive

1. As the government's opening brief explains, an integrated reading of the relevant Vaccine Act provisions shows that attorneys' fees and costs may not be awarded on an untimely petition. Under the Act's fee-shifting provision, such an award is available "on a petition filed under section 300aa-11 of this title." 42 U.S.C. 300aa-15(e)(1). As respondent stresses, the Act directs that a "proceeding for compensation under the Program * * * shall be initiated by * * * the filing of a petition." 42 U.S.C. 300aa-11(a)(1). But the Act's limitations provision qualifies that directive by stating that, "if a vaccine-related injury occurred as a result of the administration of [a covered] vaccine, *no petition may be filed* for compensation under the Program for such injury" after the expiration of the applicable time period. 42 U.S.C. 300aa-16(a)(2) (emphasis added). Because compliance with the limitations provision is a statutory prerequisite to the filing of a petition "for compensation under the Program," a petition that has been dismissed for failure to comply with the Act's time limits is not a "petition filed under section 300aa-11." And in the absence of a petition filed under Section 300aa-11, there is no statutory basis for awarding attorneys' fees and costs. See Pet. App. 14a (Bryson, J., dissenting).

2. Respondent's conception of what it means to be a "petition filed under section 300aa-11" for fee-award purposes begins and ends with Section 300aa-11 itself. See, *e.g.*, Resp. Br. 20 ("[S]ection [300aa-15(e)(1)] uses the word 'filed' to refer to the requirements of [S]ection 300aa-11."). Section 300aa-11(a)(1) states that a Vaccine Act compensation proceeding "shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by [Section 300aa-11(c)] with the" Court of Federal Claims (CFC), and it directs the clerk of the CFC to "forward the filed petition to the chief special master for assignment to a special master." Respondent argues that "a filing under section [300aa-11(a)(1)] requires two things: (1) a petition containing the matter prescribed by section 300aa-11(c); and (2), a petition that is filed with the [CFC]." *Id.* at 21; see *id.* at 22 & n.6 (contending that a Vaccine Act "pleading 'is "filed" * * * when it is delivered to, and accepted by, the appropriate court officer,'" even if it is not "'in compliance with the applicable laws and rules governing filings'") (quoting *Artuz* v. *Bennett*, 531 U.S. 4, 8 (2000)).

Respondent's argument rests on the flawed premise that Section 300aa-11 is the only Vaccine Act provision that addresses whether and how a petition may be filed. In fact, the textual correspondence among Section 300aa-11(a)(1) ("filing of a petition"), Section 300aa-15(e)(1) ("a petition filed"), and Section 300aa-16(a)(2) ("no petition may be filed") shows that Congress intended all three provisions to operate together. See, *e.g.*, *Richards* v. *United States*, 369 U.S. 1, 11 (1962) ("[It is] fundamental that a section of a statute should not be read in isolation from the context of the whole Act."). Respondent's position that Section 300aa-11(a)(1)'s reference to "filing" stands alone and unqualified would

be less at odds with the Act's text if Congress had instead crafted a limitations provision stating, for example, that "no compensation for injury or death may be paid" in connection with an untimely petition. Because such a limitations provision would address the circumstances under which relief could be awarded, rather than the circumstances under which a petition could be filed, it would not obviously qualify Section 300aa-11(a)(1) or Section 300aa-15(e)(1). But the Act's limitations provision cannot be so easily ignored when Congress phrased it in the same terms as the Act's fee-shifting provision and its provision for initiating a compensation proceeding.

That textual correspondence reveals that the specific timeliness rules of Section 300aa-16(a)(2) modify the general filing rule of Section 300aa-11(a)(1) by forbidding the filing of certain petitions. To be sure, an attorney might tender and the court clerk might accept an untimely petition for filing (an act respondent would regard as dispositive for fee-eligibility purposes). But once the special master has determined that the petition is untimely, the special master must give effect to Congress's directive in the limitations provision that "no petition may be filed," by refusing to recognize the petition as an appropriate predicate for an award of attorneys' fees and costs.

Respondent contends that, because the Vaccine Act's attorneys' fee provision (42 U.S.C. 300aa-15(e)(1)) does not specifically cross-reference the Act's limitations provision, the logical inference "is that Congress did not intend to require compliance with the statute of limitations as a prerequisite to the payment of fees incurred." Resp. Br. 25. But as the government's opening brief explains (Br. 18), that approach would suggest that

compensation may be awarded on the merits on an untimely petition because 42 U.S.C. 300aa-13 ("Determination of eligibility and compensation") likewise does not cross-reference the limitations provision. Recognizing the untenable nature of that proposition, respondent states that, with respect to other matters such as compensation on the merits, she "does not contend * * * that in order to be impacted by the statute of limitations * * * , a provision must explicitly cross-reference [42 U.S.C. 300aa-16]." Resp. Br. 27. Such an approach to when the limitations provision does and does not apply cannot be correct because it is entirely ad hoc.

Respondent's primary rationale for applying one interpretive rule to Section 300aa-11(a)(1), and a different rule to other provisions that also lack express cross-references to the limitations provision, is that the express cross-reference in Section 300aa-11(a)(2)(A) happens to fall near Section 300aa-11(a)(1). Resp. Br. 27; see *id.* at 25 (relying on *Russello* v. *United States*, 464 U.S. 16, 23 (1983)). But as the government's opening brief explains (Br. 18-19), respondent's inference is unwarranted because Congress had sound reasons to include a particularly explicit cross-reference in Section 300aa-11(a)(2)(A). Moreover, respondent is wrong to assume that the force of the *Russello* presumption is tied to the proximity within the United States Code of the two provisions under comparison. Rather, "[t]he *Russello* presumption—that the presence of a phrase in one provision and its absence in another reveals Congress' design—grows weaker with each difference in the formulation of the provisions under inspection." *Clay* v. *United States*, 537 U.S. 522, 532 (2003) (quoting *City of Columbus* v. *Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 435-436 (2002)). By that measure, the *Russello*

presumption so central to respondent's argument is particularly weak here because Section 300aa-11(a)(1) and 300aa-11(a)(2)(A), though neighbors, entirely differ in substance: They address different proceedings (a compensation proceeding versus a civil action for damages), in different fora (special masters of the CFC versus a state or federal court), through different frameworks (a procedural rule for commencing an action versus a rule preempting certain civil actions under state law).

B. The Government's Position Does Not Depend On The Premise That The Act's Statute Of Limitations Is A Jurisdictional Bar

Respondent recognizes that the government does not "make an explicit argument that the [Act's] statute of limitations is jurisdictional." Resp. Br. 32. She contends, however, that the government's position "rests upon the unstated assumption that the Act's statute of limitations functions as a jurisdictional bar." *Id.* at 33. Having attributed that position to the government, respondent and her amici then argue at length that it is wrong. See *id.* at 32-37; Nat'l Vaccine Info. Ctr. Amicus Br. (NVIC Amicus Br.) 11; Elizabeth Birt Ctr. Amicus Br. (Birt Ctr. Amicus Br.) 11-15. Contrary to respondent's contention, the government's position does not depend on the premise that the limitations provision is jurisdictional.

1. If the Act's limitations provision were jurisdictional—that is, if the CFC and special masters lacked the power to decide a petition that does not comply with the time limits in 42 U.S.C. 300aa-16—then it would follow that the CFC and special masters cannot award attorneys' fees and costs on an untimely petition. See *Brice II*, 358 F.3d at 868-869. At the time respondent ap-

pealed to the Federal Circuit, controlling precedent held that Vaccine Act provisions barring the "fil[ing]" of certain petitions were jurisdictional in nature. See *Martin*, 62 F.3d at 1405-1407; see also Pet. App. 58a n.9 (explaining that, "in the light of *Martin*," the court in *Brice II* had "assumed, without analysis, that compliance with the Vaccine Act's statute of limitations is a jurisdictional requirement"). Because of that precedent, the government's brief to the panel of the Federal Circuit in this case described the limitations provision as "an express limitation upon the jurisdiction of the [CFC]." Gov't C.A. Panel Br. 8.

Since the time that the en banc court of appeals agreed to rehear the statute of limitations issues in this case, however, the government has not taken the position that the Vaccine Act's limitations provision is jurisdictional. See Pet. App. 59a n.9 ("[The government] does not assert that the statute is 'jurisdictional.'"). This Court "ha[s] repeatedly held that filing deadlines ordinarily are not jurisdictional," instead "describ[ing] them as 'quintessential claim-processing rules.'" *Sebelius* v. *Auburn Reg'l Med. Ctr.*, 133 S. Ct. 817, 825 (2013) (quoting *Henderson* v. *Shinseki*, 131 S. Ct. 1197, 1203 (2011)). That accurately describes the Vaccine Act's statute of limitations.

Of course, this Court will treat a filing deadline as jurisdictional if "Congress has 'clearly state[d]'" as much. *Auburn*, 133 S. Ct. at 824 (brackets in original) (quoting *Arbaugh* v. *Y&H Corp.*, 546 U.S. 500, 515-516 (2006)). The Vaccine Act, however, contains no such clear statement. In particular, the Act's jurisdictional provision, 42 U.S.C. 300aa-12(a), is not constrained by the Act's limitations rule because it gives special masters broad jurisdiction "over proceedings to determine if

a petitioner under [42 U.S.C. 300aa-11] is entitled to compensation under the Program." That authority is not qualified by the limitations provision in the way that Section 300aa-11(a)(1) and Section 300aa-15(e)(1) are. Rather, the authority in Section 300aa-12(a) literally and logically includes the power to decide whether the claimant "is eligible under [42 U.S.C. 300aa-16] to file a petition for compensation." Pet. App. 14a-15a n.1 (Bryson, J., dissenting).

2. The government does not rely on an "unstated assumption" (Resp. Br. 33) that the limitations provision is jurisdictional. Respondent asserts "[t]here is no other way to explain how an untimely petition that unquestionably has been 'filed' as a matter of *fact*, can be regarded as having never been filed as a matter of *law*." *Ibid.* That is incorrect. The limitations provision operates as a non-jurisdictional affirmative defense to an award of attorneys' fees and costs to respondent, just as it operates as a non-jurisdictional affirmative defense to an award of compensation for respondent's multiple sclerosis (MS). Despite insisting that the former must involve "divest[ing] a court of jurisdiction over a petition" (*id.* at 35), respondent is content to label the latter consequence "a defense" (*id.* at 27). But there is no evident difference between the two; both are simply consequences of the government's limitations defense to an untimely petition.

In the Vaccine Act, as in numerous other laws, Congress has provided a rule in the limitations provision ("no petition may be filed" after the expiration of the applicable time period) that is adjudicated on the facts of the case, and then enforced through consequences specified by other provisions of the Act. Congress could have assigned jurisdictional significance to that frame-

work (if, for example, it had wished to permit any party to raise a timeliness objection at any time, see *Auburn*, 133 S. Ct. at 824). But Congress was not obliged to use that approach in order to withhold attorneys' fees and costs on untimely petitions, any more than it was obliged to do so in order to withhold compensation on the merits for such petitions.

C. Respondent Fails To Show How Awarding Attorneys' Fees And Costs On Untimely Petitions Would Be Compatible With The Vaccine Act's Structure And Purposes

1. As the government's opening brief explains (Br. 20-28), awarding attorneys' fees and costs on untimely petitions would be fundamentally incompatible with the Compensation Program, which is "designed to work faster and with greater ease than the civil tort system," *Bruesewitz*, 131 S. Ct. at 1073 (quoting *Whitecotton*, 514 U.S. at 269). Because untimely Vaccine Act petitions will often be dismissed with little or no inquiry by the special master into the merits of the underlying claim, the determination whether a particular claim was brought in "good faith" and with a "reasonable basis" on the merits, 42 U.S.C. 300aa-15(e)(1), would require "a sort of shadow trial to determine whether, if the claimant had made a timely filing, the petition would have had a reasonable chance of succeeding," Pet. App. 20a (Bryson, J., dissenting). Those shadow trials will tend to waste the Program's resources, are likely to be painful for many claimants and their families, and will often be more complex than the underlying proceedings on timeliness—all without any possibility of providing compensation to injured persons.

2. Respondent does not dispute that, under her approach, some further proceedings—whether called "shadow trials" or something else—will be necessary

before attorneys' fees and costs could be awarded on an untimely petition.[1] She contends only that those proceedings will not be *as* wasteful, painful, and complex as the government (and the dissenting judges below) predict. Her reasoning is unpersuasive.

First, respondent asserts that the "reasonable basis" inquiry is "routinely ma[d]e with relative ease," Resp. Br. 17, and is "straightforward" because Vaccine Act petitions are "substantiated from the outset," *id.* at 41-42. In fact, the "reasonable basis" inquiry is not always so simple. See, *e.g.*, *Silva* v. *Secretary of HHS*, No. 10-101V, 2012 WL 2890452 (Fed. Cl. Spec. Mstr. June 22, 2012) (rejecting award of attorneys' fees and costs after extensive analysis of claimant's attorneys' inadequate pre-filing investigation). And even in cases where that inquiry is straightforward, that is often because the special master has already analyzed the medical and scientific issues of causation that the petition implicates.[2] By contrast, the subset of petitions that are dismissed as untimely are particularly likely to be the

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[1] But see Resp. Br. 39 ("Having succeeded before the three judge panel on her limitations argument * * *, there can be no question that [respondent] had a * * * reasonable basis for filing her petition."). That is a *non sequitur*. Even some petitions that are *actually* timely lack "a reasonable basis for the claim for which the petition was brought," 42 U.S.C. 300aa-15(e)(1).

[2] Respondent acknowledges that the "overwhelming majority" of petitions require a showing of causation to prevail. Resp. Br. 22 n.5 (citing *Stevens* v. *Secretary of HHS*, No. 99-594V, 2001 WL 387418, at *8 (Fed. Cl. Spec. Mstr. Mar. 30, 2001). For the fraction of petitions alleging an injury based on the Vaccine Injury Table (in which causation is rebuttably presumed, see 42 U.S.C. 300aa-11(c)(1)(C)(i), 300aa-13(a)(1)), the claimant would still need to establish a reasonable basis for asserting that her injury falls within the parameters of the Table.

exception to that pattern because the underlying claim will be undeveloped on the merits. Cf. *Silva*, 2012 WL 2890452, at *12 (attributing part of a recent rise in "reasonable basis" litigation before special masters to the Federal Circuit's approval of "interim" awards of attorneys fees and costs "before the merits phase of [a] case [have] concluded"). Moreover, respondent's assertion that the "Act requires that petitions be substantiated from the outset," Resp. Br. 41, ignores both that the Act does not require the claimant's theory of causation to be articulated as part of the petition, see 42 U.S.C. 300aa-11(c), and that, notwithstanding the Act's requirements, "[i]t is not uncommon in vaccine cases for petitions to lack complete medical records," *McKellar* v. *Secretary of HHS*, 101 Fed. Cl. 297, 303 (2011).

To be sure, the government has determined in some prior cases that the Program's resources will be best conserved by simply acquiescing in relatively modest attorneys' fees and costs awarded on what it believes is an overly lax application of the reasonable-basis standard. Respondent identifies some such cases, as well as some cases in which attorneys' fees and costs were denied because the petitions were facially baseless. Resp. Br. 43. But there is no reason to think those cases would be representative of fee proceedings on the increased number of untimely petitions that respondent's position would encourage. More importantly, two wrongs do not make a right; the solution to the waste and complexity of shadow trials is to withhold attorneys' fees and costs in the first place, as Congress intended, not to relax the reasonable basis determination out of existence, as respondent would.

Second, respondent (joined by her amici) contends that a special master will be particularly well-situated,

by virtue of having decided that a petition is untimely, to make a swift determination whether there was a reasonable basis on the merits for the underlying claim. See Resp. Br. 38-45; NVIC Amicus Br. 15-16; see also *id.* at 21-22 (making related claim that the timeliness inquiry is complicated by questions of causation); Birt Ctr. Amicus Br. 11 (similar). That argument has no basis in law, logic, or medicine. As a matter of law, in respondent's own case the en banc Federal Circuit overruled (Pet. App. 51a-57a) the panel's holding (*id.* at 95a-102a) that limitations and causation issues were intertwined such that medical recognition of a causal link between vaccine and injury was a prerequisite to the running of the limitations period. As a matter of logic, there is no reason to think that evidence about *when* an injury first manifested will routinely shed light on *why* it occurred. And as a matter of medicine, the timeliness determination—which turns on "the date of the occurrence of the first symptom or manifestation of onset" of the claimed injury, 42 U.S.C. 300aa-16(a)(2)—is a diagnostic question of what symptoms and signs (*e.g.*, respondent's "electric shock sensation in her spine," Resp. Br. 7-8) indicate that a person has a particular condition (*e.g.*, MS). By contrast, the determination whether a vaccine caused that condition (*e.g.*, whether the Hepatitis-B vaccine in fact caused petitioner's MS) calls for a very different set of evidence and expertise.

Tellingly, respondent offers no concrete example—actual or hypothetical—of a case in which the limitations inquiry would fully prepare the special master to decide whether the claimant had a reasonable basis for claiming that a vaccine caused her injury. Particularly puzzling is respondent's reliance on the case the government offered to illustrate the potential complexity of a

shadow trial, *Smith* v. *Secretary of HHS*, No. 02-93V, 2006 WL 5610517 (Fed. Cl. Spec. Mstr. July 21, 2006), sustained, 2006 WL 5624674 (Fed. Cl. Nov. 16, 2006). The special master held the petition in *Smith* untimely based on his conclusion that the claimant's excessive thirst and frequent urination were symptoms of diabetes. See Pet. Br. 24-25. Yet respondent asserts (without explanation) that, having determined that excessive thirst and frequent urination are symptoms of diabetes, the special master would find it a "simple matter," Resp. Br. 45 n.12, to conclude that the claimant had a reasonable basis for asserting that various childhood vaccines caused his type 1 diabetes. Common sense suggests that inquiry would be anything but "simple."[3]

3. Respondent's amici contend that reversing the decision below would "decrease participation in the [P]rogram," NVIC Amicus Br. 13, "further dissuade

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[3] Other petitions recently denied as untimely readily illustrate the point that limitations and causation issues are distinct. See, *e.g.*, *Wilkerson* v. *Secretary of HHS*, 593 F.3d 1343 (Fed. Cir. 2010) (whether there is a reasonable basis for the claim that childhood vaccines cause attention deficit hyperactivity disorder (ADHD) would be distinct from determination that the first symptom of claimant's ADHD occurred more than 36 months before petition was filed); *Davis* v. *Secretary of HHS*, No. 09-346V, 2009 WL 5196168 (Fed. Cl. Spec. Mstr. Dec. 18, 2009) (whether there is a reasonable basis for the claim that trivalent influenza vaccine causes chronic chest pain would be distinct from determination that the first symptom of claimant's chest pains occurred more than 36 months before petition was filed); *Carson* v. *Secretary of HHS*, No. 02-873V, 2009 WL 2957312 (Fed. Cl. Spec. Mstr. Aug. 26, 2009) (whether there is a reasonable basis for the claim that the vaccine preservative Thimerosal causes autism spectrum disorder would be distinct from determination that first symptom of claimant's autism spectrum disorder occurred more than 36 months before petition was filed), aff'd, 97 Fed. Cl. 620 (2010), appeal pending, No. 2010-5089 (Fed. Cir. docketed Mar. 4, 2010).

attorneys from participating in the [P]rogram," *id.* at 22, "drive lawyers away," Birt Ctr. Amicus Br. 4, and "further skew" representation in the Program, *id.* at 10. Those concerns are unfounded because attorneys have *never* had a reasonable expectation of an award of fees and costs on an untimely petition. Until the decision below, the court of appeals had *never* approved such an award, and had held instead that attorneys' fees and costs were categorically unavailable for untimely petitions. See *Brice II*, 358 F.3d at 868-869; *Hebern* v. *Secretary of HHS*, 81 Fed. Appx. 333 (Fed. Cir. 2003) (per curiam) (unpublished); cf. *Martin*, 62 F.3d at 1405-1407. For efficiency's sake, the government has acquiesced in some small awards made in non-precedential decisions on petitions that the government had argued were untimely; but the government has never endorsed the principle that fees may be awarded on untimely petitions. It is therefore the decision below, and respondent's position, that would upset the status quo. And the natural but undesirable result of breaking with consistent practice would be an increase in the number of untimely Vaccine Act petitions. See Pet. Br. 26-27.[4]

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[4] The Vaccine Act states that "[n]o attorney may charge any fee for services in connection with a petition filed under section 300aa-11 of this title which is in addition to any amount awarded as compensation by the special master or court." 42 U.S.C. 300aa-15(e)(3). Because that bar on charging additional fees applies only to services rendered "in connection with a petition filed under section 300aa-11," it does not preclude the charging of fees for the preparation of untimely petitions. See NVIC Amicus Br. 23-24. So far as we are aware, however, attorneys did not engage in any such practice during the years before the en banc decision below, when extant Federal Circuit precedents precluded fee awards on untimely petitions. If this Court reverses the judgment below, the more likely result is that attorneys will diligently investigate the timeliness of the petitions they file and accept

Finally, there is no force to the suggestion that attorneys' fees and costs should be awarded on untimely petitions because Vaccine Act claimants are outmatched by the government in compensation proceedings. See Birt Ctr. Amicus Br. 3-4, 10. Respondent's amicus does not explain how awarding attorneys' fees and costs on untimely petitions would equalize the parties' resources in proceedings on the merits of other petitions. But in any event, amicus is mistaken in asserting that the government has "greater funds" that exert a "significant tilt," *id.* at 10, in its favor in Vaccine Act proceedings. To the contrary, there is remarkable parity in the Program: Over the past five fiscal years, appropriations to the Department of Justice and the Department of Health and Human Services for attorneys, experts, and administrative costs related to the Vaccine Act have totaled $68.44 million, while total awards of fees and costs to claimants have totaled $69.09 million.[5] And the

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the risk of nonpayment upon a finding of untimeliness as a cost of doing business (as attorneys often must do when their compensation depends on obtaining a fee award from the court). And as one of the amici's examples of its own good offices illustrates, established *pro bono* representation is available to claimants facing potential timeliness obstacles. See *id.* at 26-27 (discussing representation provided by George Washington University Law School Vaccine Injury Clinic).

[5] For Fiscal Years 1990 through 2012, the corresponding cumulative figures are approximately $186 million and $156 million. The government's actual administrative expenditures on compensation proceedings are somewhat less than the stated figures because appropriations to the Department of Health and Human Services are also used for other purposes, such as rulemaking and studies under contract with the Institute of Medicine related to the Vaccine Injury Table (see 42 U.S.C. 300aa-14(c)), as well as supporting the Advisory Commission on Childhood Vaccines (see 42 U.S.C. 300aa-19). Upon request, the government will lodge with the Clerk the appropriations

assertion that the government "prevail[s] in the overwhelming majority of cases," *ibid.*, is true only if one includes the thousands of petitions unsuccessfully asserting that certain vaccines cause autism spectrum disorder. See Advisory Comm'n on Childhood Vaccines, Dep't of HHS, *The National Vaccine Injury Compensation Program (VICP)* 4 (Dec. 6, 2012) (summary figures for disposition of petitions in recent years), http://www.hrsa.gov/vaccinecompensation/accvdvic120612.pdf. The best inference from those figures is not that the Compensation Program is "skew[ed]," Birt Ctr. Amicus Br. 10, but rather that the inducement of attorneys' fee awards has invigorated the Vaccine Act claimants' bar to pursue successful claims, as well as other claims that are reasonable but are ultimately found to be unmeritorious. That is further confirmation that the Program is functioning as Congress intended, under a fee-shifting framework that has never before included the rule respondent urges.

D. Respondent Misconceives And Misapplies The Relevant Canons Of Statutory Construction

1. As the government's opening brief explains (Br. 28-34), three canons of statutory construction reinforce the conclusion that attorneys' fees and costs are not available when a Vaccine Act petition is dismissed as untimely. First, because Vaccine Act fee awards are money judgments paid from the Treasury, they directly implicate the principle that waivers of sovereign immunity are narrowly construed. Second, interpreting the Act to allow fee awards on untimely petitions is disfavored because it would substantially depart from the

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legislation and fee award information underlying these figures, of which this Court could take judicial notice. See Sup. Ct. R. 32.3.

common law principles that have traditionally governed the question of who bears responsibility for legal expenses. Third, construing the Act to avoid lengthy and complex fee proceedings would respect this Court's admonition that a "request for attorney's fees should not result in a second major litigation." *Hensley* v. *Eckerhart*, 461 U.S. 424, 437 (1983).

Respondent flouts those principles by misconceiving the question presented as whether the Act's provision for attorneys' fees and costs "should be construed to contain a categorical exception prohibiting the payment of fees incurred on [an untimely] petition." Resp. Br. i. To characterize the government's argument as a request for an "exception" (*id.* at i, 2, 7, 14, 17, 18, 20, 46, 47, 48) gets the matter exactly backwards. Under the applicable canons of statutory construction, this Court does not presume that Congress intended the sovereign to pay an opposing party's attorneys' fees in derogation of the common law following a cumbersome fee litigation—and then look for exceptions. Rather, the Court presumes that Congress would not intend such awards, and the burden is on the fee applicant to rebut that presumption by identifying clear evidence of congressional intent to allow them. Neither the text, the structure, nor the purposes of the Vaccine Act offer any indication (let alone a clear indication) that Congress intended such awards.

2. Respondent fares no better in her limited attempts to argue that the canons of construction noted above do not apply here or have been overcome.

a. With respect to sovereign immunity, respondent has taken on the unenviable task of arguing that a claim brought against the Head of a Department in her official capacity, seeking money to be drawn from the Treasury,

does not implicate principles of sovereign immunity. Respondent contends that those characteristics are not dispositive because the Compensation Program could be analogized to a commercial insurance system. But as the government's opening brief explains (Br. 29-32), the Compensation Program is not a system of commercial insurance. Respondent's efforts to rebut that showing are unpersuasive.

First, respondent cites a treatise on insurance law for the proposition that "compensation funds are 'treated as a trust fund'" that "'will not be entitled to sovereign immunities.'" Resp. Br. 50 (quoting 2 Lee R. Russ & Thomas F. Sewall, *Couch on Insurance* § 10:12, at 10-32 to 10-33 (3d ed. 1995)). Respondent fails to note that the cited discussion is specific to workers' compensation policies. For such policies, the "employer [may have] a choice between private insurance, self-insurance, and state funds," and "courts almost unanimously hold that the [state workers' compensation] fund is a private trust to be administered by the state commission." 1A Steven Plitt et al., *Couch on Insurance* § 10:12, at 10-30 to 10-31 (3d rev. ed. 2010). Just as "[w]hen the United States went into the insurance business" in *Standard Oil Co.* v. *United States*, 267 U.S. 76, 79 (1925), a State issuing a workers' compensation policy is in the insurance business. By contrast, creating the Compensation Program—which does not accept premiums, does not write policies, and is not subject to principles of trust law—did not put the United States into the insurance business.

Second, respondent contends (Br. 50) that principles of sovereign immunity do not apply to the Program because it is "unsubsidized." Respondent apparently means that current Program awards do not exceed the amount collected by the excise tax on vaccine doses, and

are not supplemented by additional appropriations from revenues raised in other ways. Respondent offers no authority, however, for the proposition that the application of sovereign-immunity principles depends on the type of revenue-raising measure that finances a particular government program.

Acceptance of respondent's argument could have far-reaching implications. Numerous trust funds in the Treasury are associated with standing appropriations linked to particular taxes. See, *e.g.*, 26 U.S.C. Ch. 98, Subch. A. For example, the Federal Disability Insurance Trust Fund, which pays Social Security disability (SSD) insurance benefits, is funded by a standing appropriation of a percentage of taxable wages and self-employment income reported under the tax code. See 42 U.S.C. 401(b) and (h). That arrangement is analogous to the Vaccine Act's structure in all relevant respects. Yet this Court has "ha[d] no difficulty agreeing with" the proposition that the time limit for seeking review of SSD benefit determinations is a "condition on the waiver of sovereign immunity and thus must be strictly construed." *Bowen* v. *City of New York*, 476 U.S. 467, 479 (1986). Respondent's position that principles of sovereign immunity are inapplicable to the Vaccine Act (see Pet. Br. 31-32 & n.2) is in significant tension with this Court's readiness to apply those principles in the SSD context.

b. Respondent does not dispute that the "canon that caution should be used when interpreting statutes that are in derogation of the common law" (Resp. Br. 50-51) applies here and disfavors her position. Her only response is that "Congress was unmistakably clear in providing for the payment of attorneys' fees incurred in connection with petitions that are denied." *Id.* at 51.

But the question presented here is whether Congress was "unmistakably clear" in particularly authorizing such awards in connection with *untimely* claims—claims for which Congress directed that "no petition may be filed," 42 U.S.C. 300aa-16(a)(1). Even if the Act were not clear in *forbidding* such awards, it is certainly not "unmistakably clear" in *authorizing* them, a conclusion reinforced by the 7-to-6 division in the en banc court below.

c. Respondent contends that this Court's disapproval of complex attorneys' fee litigation, see *Hensley*, *supra*, is irrelevant here because Section 300aa-15(e)(1) "is not a true 'fee-shifting' provision" in that "the United States does not pay the fees that might otherwise be paid by claimants." Resp. Br. 51, 5 n.2. Similarly, an amicus contends that fee awards under the Act are better analogized to awards from a common fund. NVIC Amicus Br. 9-11.

Those arguments are unpersuasive because they dispute the "fee-shifting" label without addressing *Hensley*'s underlying precept that a "request for attorney's fees should not result in a second major litigation," 461 U.S. at 437. Whatever the label or theory on which fees are awarded, it is fair to presume that Congress intended to minimize the time and resources expended on collateral proceedings for deciding the availability and amount of attorneys' fees and costs. If such an award is potentially available on an untimely Vaccine Act petition, then the claimant's attorney will be able to obtain additional fees from the Compensation Fund for pursuing the fee application itself, including conducting any shadow trial. See Pet. App. 20a-21a (Bryson, J., dissenting). By the same token, the government's attorneys will be engaged in responding to the fee application and

participating in the shadow trial rather than addressing other claims on the merits, and the limited resources of the special masters will be diverted to complex fee proceedings that cannot possibly result in compensation for injured persons. *Hensley*'s common-sense approach to fee litigation teaches here that Congress never envisioned such wasteful proceedings in the first place.

* * * * *

For the foregoing reasons and those stated in our opening brief, the order of the court of appeals should be vacated, and the case remanded with instructions to deny respondent's motion for an award of attorneys' fees and costs.

Respectfully submitted.

DONALD B. VERRILLI, JR.
Solicitor General

MARCH 2013

AMICUS CURIAE BRIEF

RECORD AND BRIEFS

No. 12-236

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IN THE

Supreme Court of the United States

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

MELISSA CLOER,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF *AMICUS CURIAE* OF ELIZABETH BIRT CENTER FOR AUTISM LAW AND ADVOCACY, *et al.* IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Does the Vaccine Act[1] prohibit attorneys from being paid when they bring reasonable, good faith claims that a court ultimately finds to be untimely?

1. The Vaccine Act, which established the Vaccine Injury Compensation Program, is located at 42 U.S.C. §§ 300aa-1 *et seq.* For convenience, future references will be to the "Vaccine Act," the "Act" or the "Vaccine Program." Individual sections to the Act will include only the section number.

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IDENTITY AND INTEREST OF *AMICI CURIAE*

The *amici* respectfully submit this brief *amicus curiae* in support of Respondent Melissa Cloer[1] pursuant to Supreme Court Rule 37. The organizations that have signed this brief seek that the Court decides this case impartially and in keeping with Congressional intent. A full list of the *amici* is attached as Exhibit A. All the undersigned organizations understand that Congress intended to create a generous program to compensate the innocent victims of vaccine injury. This generosity included the right to have competent counsel.

Many of the organizations advocate for the ethical principle of informed consent to vaccination, as every vaccination potentially carries the risk of injury or death. Several organizations advocate for the rights of individuals with autism spectrum disorders, which have been associated with vaccine injury. Others highlight the risks of mercury in all medicines, including vaccines. The *amici* all interpret the Vaccine Act to require attorneys to be paid when they bring good faith, reasonable claims, even if a court ultimately finds them to be untimely. This interpretation best reflects Congress' generous intent.

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1. Pursuant to this Court's Rule 37.2, all parties with counsel listed on the docket have consented to the filing of this brief. Letters evidencing such consent have been filed with the Clerk of the Court. Pursuant to Rule 37.6, Amicus Curiae affirms that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than Amicus Curiae, its members, or its counsel made a monetary contribution to its preparation or submission.

SUMMARY OF ARGUMENT

The plain language of the Vaccine Act provides that special masters pay attorneys' fees and costs to unsuccessful petitioners if the petitions were filed in good faith and on a reasonable basis. The statute does not limit attorneys' fees to timely petitions.[2]

Due to the often subtle and confusing nature of the onset of vaccine injury symptoms, the exact date of onset is often unknown and heatedly contested. *See Wilkerson v. Sec'y of HHS*, 593 F.3d 1343 (Fed. Cir. 2010). Congress intended that petitioners have competent counsel to address such complex issues at every step in the proceedings – even when making good faith, reasonable arguments at the outset as to whether petitions are timely filed.

Remedial legislation created the Vaccine Injury Compensation Program (Vaccine Program). *See Cloer v. Sec'y of HHS*, 654 F.3d 1322, 1350 (Fed. Cir, 2011) (noting the "remedial nature" of the Vaccine Program). Congress sought to promote the nation's public health by limiting civil lawsuits against vaccine manufacturers. A key part of the Congressional scheme was to provide generous compensation for those inadvertently injured by vaccines. *See Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1079 (2011) (describing the Vaccine Program as a "generous compensation scheme").

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2. *Amici* acknowledge that the reasons for an untimely filing may well be relevant to whether the filing was in good faith and had a reasonable basis.

There is nothing generous in requiring parents of vaccine-injured children to pay attorneys to argue legitimate timeliness claims. Certainly, Congress did not intend to limit access to the Vaccine Program to those who could afford to pay the "entry fee."

Congress did not intend that access to the Vaccine Program be limited only to those with the funds to compete with a formidable opponent. The Secretary of Health and Human Services and the Department of Justice vigorously defend against vaccine injury claims. They often hire many scientific and medical experts to testify as to when the onset of symptoms occurred for purposes of determining whether a claim was timely filed.[3] For example, in *Cedillo v. Sec'y of HHS*,[4] a petitioner claimed that she suffered brain damage and autism as a result of vaccination. To defeat her claims, the government provided twenty-two (22) different physicians and scientists to testify. *Id.* Clearly, Congress did not intend that access to the Vaccine Program be limited to those with sufficient financial resources to compete with a formidable opponent. Instead, as the Federal Circuit recently emphasized, "[O]ne of the underlying purposes of the Vaccine Act was to ensure that vaccine injury claimants have readily available a competent bar to prosecute their claims." *Avera v. Sec'y of HHS*, 515 F.3d 1343, 1352 (Fed. Cir. 2008).

Denial of payment for attorneys' fees and costs in good faith, reasonable cases would undoubtedly have a chilling

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3. *See Wilkerson v. Sec'y of HHS*, 593 F.3d 1343 (Fed. Cir. 2010).

4. 617 F.3d 1328 (Fed. Cir. 2010).

effect on the Vaccine Program. It would drive lawyers away from representing clients in the Program; it would push legitimate vaccine injury cases into the civil courts; it would increase the number of *pro se* claimants; and in direct conflict with congressional intent, would likely undermine public confidence in federal vaccine policy. Finally, the Court of Federal Claims has clear jurisdiction to award, or deny fees in untimely filed cases, in contrast to Petitioner's contention.

ARGUMENT/REASONS TO DENY THE WRIT

1. Statutory Interpretation Supports Payment of Attorneys' Fees In Cases Where a Petition is Filed in Good Faith and With Reasonable Basis

A. Plain Meaning of § 15(e)(1)

The Vaccine Act's plain language permits the payment of attorney's fees "if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought." § 15(e)(1). Good faith and reasonable basis are the ***only*** limitations for attorneys' fees. No language in the statute prohibits payment of attorneys' fees if a court ultimately finds a claim to be untimely. The statute prohibits only petitions filed in bad faith or without a reasonable basis.

The exact timing of the onset of vaccine injury symptoms may be extremely difficult to ascertain.[5]

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5. Unlike § 16(a)(3), which establishes a clear filing deadline of two years in vaccine-related death cases, § 16(a)(2) provides an unclear deadline. It is 3 years after the "occurrence of the first symptom or manifestation of onset . . .of such injury. . . ."

Indeed, many autistic children currently processing claims in the Vaccine Program face precisely this issue. Many require substantial legal proceedings simply to determine whether their petitions were timely filed. As Judge Futey noted:

> [T]he beginning stage of autism cannot be reduced to a single, identifiable symptom. . . .Many of the initial 'symptoms' are subtle and can easily be confused with typical childhood behavior. . . .Where there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on 'the occurrence of the first symptom.'

Setnes v. Sec'y of HHS, 57 Fed.Cl. 175, 179 (USCFC 2003).

Congress sought to give such petitioners the financial resources to argue timeliness issues and to keep these claims out of state and federal civil courts.[6]

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6. In *Brice v. Sec'y of HHS*, 240 F.3d 1367 (Fed. Cir. 2001) ("*Brice I*"), Judge Dyk perspicaciously observed, "We need not decide in this case whether a petitioner who fails to file a timely petition under the Program may still pursue traditional tort remedies." *Brice*, 240 F.3d at 1368. The answer to this question is both relevant and important. Certainly, vaccine manufacturers will argue that untimely filings by autistic children in the Program will cut off traditional state tort remedies. Indeed, the number one purpose of the Vaccine Act is to shield vaccine manufacturers from lawsuits. However, *amici* point out, all fifty (50) states toll statutes of limitations for minors and for brain-damaged individuals. It is inconceivable that congress would have intended such a sweeping preemption of the rights of children and mentally handicapped persons without a single word in the statute. What does the statute

B. Congress Intended to Pay Attorneys' Fees for Petitions Filed In Good Faith and With Reasonable Basis

Prior to the existence of the Vaccine Program, civil lawsuits against vaccine manufacturers abounded. When vaccine manufacturers threatened to stop making vaccines due to the crippling costs of litigation, the nation's health programs were also threatened and a crisis ensued. Congress responded by establishing the Vaccine Program in 1988 to ensure the availability of existing vaccines and to encourage the development of new ones. Congress accomplished this by prohibiting lawsuits against vaccine manufacturers and by requiring that people claiming vaccine injuries first present their claims in the Vaccine Program. While Congress preserved the rights of claimants to file civil actions if the Vaccine Program failed to resolve their claims, Congress painstakingly designed the Program to minimize this likelihood. It designed a "no fault," generous Program. §§ 15(a)(1-4). The Vaccine Program was designed to be "less adversarial, expeditious, and informal [with]. . .flexible and informal standards of [the] admissibility of evidence." §§ 12(d)(2)(A) & (B). While permitting post-Program civil actions,

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say? The Vaccine Act expressly states that, except as otherwise provided, "State law shall apply to a civil action brought for a vaccine-related injury or death." § 22(a). The Vaccine Act does not provide that untimely petitioners in the Program forfeit all rights to civil litigation. Indeed, such an interpretation is incongruous with congressional intent and will be firmly rejected by state courts.

Congress made such actions more difficult by limiting theories of liability[7] and by requiring phased trials. § 23.

Congress' "principal findings" that led to the Vaccine Program are still relevant today. They are:

> 1. [t]he availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities;
>
> 2. [t]he Federal government has the responsibility to ensure that all children in need of immunization have access to them and to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries; and
>
> 3. [p]rivate or non-governmental activities have proven inadequate in achieving either of these goals. . . .

H.R. Rep. No. 99-908, 99th Cong., 2d. Sess. page 5 (1986).

Thus, Congress stated, "two overriding concerns have led to the development of this legislation:

> (a) the inadequacy--from both the perspective of vaccine-injured persons as well as vaccine manufacturers--of the current approach to compensating those who have been damaged by a vaccine; and

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7. *See* § 22; *see also Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1079 (2011).

> (b) the instability and unpredictability of the childhood vaccine market. . . ."

Id. at 7.

To remedy these concerns, Congress created the Vaccine Program. Congress hoped the Vaccine Program would lessen the number of lawsuits against manufacturers. In so doing, it hoped the Vaccine Program would promote the "development of both new and improved vaccines. . . ." *Id.* at 4. It also hoped it would help to create, "a new system for compensating individuals who have been injured by vaccines routinely administered." *Id.* at 3. Congress intended awards to petitioners to "be made... quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908 at 18; U.S. Code Cong. & Admin. News 1986, page 18.

Congress also intended that the Program itself pay attorneys' fees and costs, not petitioners. For this reason, § 15(e)(3) prohibits attorneys from receiving compensation "in addition to" that provided by the Program. However, Congress said, "The Committee. . . .intends that the court make adequate provision for attorneys' time and that the court exercise its discretion to award fees in non-prevailing, good faith claims." H.R. Rep. No. 99-908 at 22. There is no mention of timeliness.

Congress sought to make the Program attractive by relieving petitioners of the onerous burden of contingent attorney fees and extraordinary case expenses. The Program pays reasonable attorney fees for petitions filed in good faith with a reasonable basis. §§ 15(e)(1) & (3).

This brief, however, is not about attorneys' fees. It is about an interpretation of the Court's jurisdiction in a way that promotes, not undermines, congressional intent. It is about minimizing lawsuits against vaccine manufacturers. As Justice Souter noted:

> For injuries and deaths traceable to vaccinations, the Act establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system. H. R. Rep. No. 99-908, pp. 3-7 (1986). Special masters in the Court of Federal Claims hear vaccine-related complaints, 42 U.S.C. § 300aa-12(c) (1988 ed., Supp. V), which they adjudicate informally, §300aa-12(d)(2), within strict time limits, §300aa-12(d)(3)(A), subject to similarly expeditious review, §300aa-12(e)(2). A claimant. . .must exhaust the Act's procedures and refuse to accept the resulting judgment before filing any *de novo* civil action in state or federal court. 42 U.S.C. § 300aa-11(a) (1988 ed. and Supp. V).

Shalala v. Whitecotton, 514 U.S. 268, 269-270 (1995) (emphasis added).

Simply put, Congress' primary purpose in establishing the Vaccine Program was to promote the nation's health by protecting its current supply of vaccines and by encouraging the development of new vaccines.[8] *See* H.R.

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8. Since the Vaccine Program was established, the following vaccines have been developed and added to the Vaccine Table: Diphtheria-Tetanus-acellular-Pertussis ("DTaP") vaccine;

Rep. No. 99-908, 99th Cong., 2nd. Sess. (1986). Due to the "no fault," informal and generous nature of the Program, Congress intended that most, if not all, claims for vaccine-related injuries would be resolved in the Program without resort to civil litigation.

C. Congress Intended that Petitioners Have the Resources to Compete Against a Formidable Opponent

Few would argue that there is already a significant tilt in the Vaccine Program in favor of the Secretary of Health and Human Services and the Department of Justice. They prevail in the overwhelming majority of cases. They have greater funds, experience, access to experts and access to science scientific data from the government than petitioners have. To threaten petitioners' counsel with non-payment of fees in good faith, reasonable cases will only further skew this already uneven playing field and further undermine public confidence in federal vaccine recommendations.

Few qualified attorneys are now willing to accept vaccine injury cases because they are exceedingly difficult to litigate. If the government prevails in this case, the Court of Federal Claims will undoubtedly have even more *pro se* litigants because counsel will be unwilling to take any but the most clear-cut cases.

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hepatitis B vaccine, *haemophilus influenzae* type B vaccine, varicella vaccine, rotavirus vaccine, pneumococcal conjugate vaccines, hepatitis A vaccine, trivalent influenza vaccine, and human pappillomavirus vaccine.

2. The Onset of Symptoms Is Often Subtle and Confusing

Scientists often do not know how vaccines cause injury. This lack of knowledge, combined with the introduction of new vaccines and evolving science, profoundly impacts any understanding of when an "onset" of symptoms occurs. Because of this lack of knowledge, the "preponderance" standard invites good faith debate between the parties. Petitioners with good faith, reasonable arguments have a statutory right to have their lawyers paid. As the Federal Circuit has noted, "[T]he purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

3. The Court has Jurisdiction to Award Fees in Untimely Cases

In *Brice I* and *Brice v. Sec'y of HHS*, 358 F.3d 865 (Fed. Cir. 2004)("*Brice II*"), the Federal Circuit ruled that the Vaccine Act is a waiver of sovereign immunity, and that courts have no subject matter jurisdiction to award fees in untimely cases. However, several decisions after *Brice II* by both the Federal Circuit and this Court indicate that "waivers of sovereign immunity" and "jurisdiction" are slippery concepts that are not well-defined. In the end, they are simply two of many tools courts use to interpret federal statutes. The primary tools, however, are plain language of the statute and Congressional intent.

For example, after *Brice II* was decided, the Federal Circuit ruled that a plaintiff's failure to timely file a claim

does *not* affect the subject matter jurisdiction of the Court of Federal Claims. *Venture Coal Sales Co. v. U.S.*, 370 F.3d 1102, 1105, n.2 (Fed. Cir. 2004). Thereafter, the Federal Circuit ruled "the Supreme Court has 'clarified that time prescriptions, however emphatic, are not properly jurisdictional.'" *Kirkendall v. Dept. of the Army*, 479 F.3d 830, 842 (Fed. Cir. 2007).[9]

Regarding the slippery concept of jurisdiction, this Court has indicated that "Clarity would be facilitated if courts and litigants used the label 'jurisdictional' not for claim-processing rules, but only for prescriptions delineating the classes of cases (subject-matter jurisdiction) and the persons (personal jurisdiction) falling within a court's adjudicatory authority." *Kontrick v. Ryan*, 540 U.S. 443, 455 (2004). This Court made a further distinction regarding how time limitations should be construed in terms of jurisdiction in *Eberhart v. U.S.*, 546 U.S. 12, 16 (2005). In *Eberhart*, this Court stated, "Our repetition of the phrase 'mandatory and jurisdictional' has understandably led the lower courts to err on the side of caution by giving [time] limitations. . .the force of subject-matter jurisdiction. *Id.* at 19.[10]

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9. In his dissent, Judge Dyk, who wrote the decision in *Brice II*, admittedly recognized that recent precedential "cases have admittedly clouded the 'jurisdictional nature' of time bars." *Id.* at 872.

10. This Court termed time limitations as "claim-processing rules, despite the confusion generated by the 'less than meticulous' uses of the term 'jurisdiction' in our earlier cases (citing *Kontrick*, 540 U.S. at 454)." *Id.* at 16.

The following year, this Court further clarified, "[I]n recent decisions we have clarified that time prescriptions, however emphatic, 'are not properly typed "jurisdictional."'" *Arbaugh v. Y & H Corporation*, 546 U.S. 500, 510 (2006).[11] To rule out any question, this Court again addressed this issue, in *Day v. McDonough*, stating, "A statute of limitations defense is ***not*** jurisdictional. . . ." 547 U.S. 198, 199 (2006) (emphasis added).

The Federal Circuit's decision in *John R. Sand & Gravel Company v. U.S.*[12] demonstrated a clear difference of opinion among Federal Circuit judges with respect to subject matter jurisdiction and untimely filings. The Federal Circuit solely reviewed whether failure to meet the Tucker Act's six-year statute of limitations[13] deprived the Court of Federal Claims of subject matter jurisdiction. The majority opinion recognized that recent Supreme Court decisions have described time limitations as non-jurisdictional claim processing rules. *Id.* at 1354. However, the Court insisted, a plaintiff's failure to meet the Tucker Act's time limitation is jurisdictional and did deprive the Court of Federal Claims of jurisdiction to enforce the claim. *Id.* at 1346. In her dissent, Judge Newman cited a litany of decisions, many cited here, that explicitly state that the Court of Federal Claims' subject matter

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11. Further explaining this Court's position, the majority stated, "We have described such unrefined dispositions as 'drive-by jurisdictional rulings' that should be accorded 'no precedential effect' on the question whether the federal court had authority to adjudicate the claim in suit." *Id.* at 511.

12. 457 F.3d 1345 (Fed. Cir. 2006).

13. Located at 28 U.S.C. § 2501.

jurisdiction is *not* affected by statutory bars to remedies, such as time limits.[14] *Id.* at 1362.

This Court agreed with the Federal Circuit's majority. It found the Tucker Act's statute of limitations to be jurisdictional. The Tucker Act, however, is not the Vaccine Act. The Tucker Act provides compensation for damages from government-mandated environmental remedial action. The Supreme Court's characterization of the Act's statute of limitations as jurisdictional was *consistent* with congressional intent. Nothing in the *John R. Sand & Gravel Company* ruling undermines the Congress' purpose of establishing the Tucker Act. The primary purpose of the Vaccine Act, on the other hand, is to resolve vaccine injury cases in the Vaccine Program, not in civil court. To deprive the Court of Federal Claims its power to implement provisions, such as § 15(e), designed by Congress to promote its goal of resolving vaccine injury cases in the Vaccine Program, is in direct conflict with congressional intent.

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14. Judge Newman cited, *inter alia*, "*Ariadne Fin. Servs. Pty. Ltd. v. U.S.*, 133 F.3d 874, 878 (Fed. Cir. 1998), ('the question of a time bar on [plaintiff's] claim does not affect the subject matter jurisdiction of the Court of Federal Claims'); *Henke v. U.S.*, 60 F.3d 795,798 n.3 (Fed. Cir. 1995) ('The raising of the statutory bar to a remedy does not, as such, deprive the court of jurisdiction to hear the cause in the first instance. Indeed, the court could not adjudicate the question of the proper application of the statute if it did not have subject matter jurisdiction over the claim'); [and] *Borough of Alpine v. U.S.*, 923 F.2d 170, 171 n.1 (Fed. Cir. 1991) (despite an untimely filing the 'Claims Court has and will continue to have jurisdiction over the subject matter of Contract Disputes Act cases')." 457 F.3d 1363.

This Court has recently confirmed this common sense approach. The Supreme Court stated, "The sovereign immunity canon is just that – a canon of construction. It is a tool for interpreting the law, and we have never held that it displaces the other traditional tools of statutory construction." *Richlin Security Service Company v. Michael Chertoff, Sec'y of Homeland Security*, 128 S.Ct. 2007, 2019 (2008).

In this case, the doctrine of sovereign immunity should play no role. The plain language of § 15(e) of the Vaccine Act and Congress' intent remove all ambiguity. The Court of Federal Claims has jurisdiction to award fees and should do so.

CONCLUSION

The *en banc* decision of the U.S. Court of Appeals for the Federal Circuit should be affirmed.

Respectfully submitted,

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APPENDIX

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Age of Autism (www.ageofautism.com)

Alan D. Clark, M.D. Memorial Research Foundation

Alliance for Human Research Protection (www.ahrp.org)

Autism Action Network (www.a-champ.org)

AutismOne (www.autismone.org)

The Canary Party (www.canaryparty.org)

The Center for Personal Rights (www.centerforpersonalrights.org)

Citizens for Health (www.citizens.org)

The Coalition for Safe Minds (www.safeminds.org)

Generation Rescue (www.generationrescue.org)

Maryland Coalition for Vaccine Choice (mdvaccinechoice.wordpress.com)

National Autism Association (NAA) (www.nationalautismassociation.org)

Appendix A

National Autism Association New York Metro Chapter
(www.naanyc.org)

The Office of Medical & Scientific Justice
(www.omsj.org)

Schafer Autism Report (www.sarnet.org)

Truth About Gardasil (www.truthaboutgardasil.org)

Unlocking Autism (www.unlockingautism.org)

Vermont Coalition for Vaccine Choice
(www.vaxchoicevt.org)

We the Parents (www.wetheparents.info)

AMICUS CURIAE BRIEF

SUPREME COURT, U.S.
FILED
FEB 11 2013
OFFICE OF THE CLERK

No. 12-236

IN THE

Supreme Court of the United States

KATHLEEN SEBELIUS, SECRETARY
OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

MELISSA CLOER,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMICI CURIAE BRIEF OF THE NATIONAL VACCINE INFORMATION CENTER, THE VACCINE INJURED PETITIONERS BAR ASSOCIATION, AND THE GEORGE WASHINGTON UNIVERSITY LAW SCHOOL VACCINE INJURY CLINIC IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Does the Vaccine Act* prohibit payment of attorneys' fees where a claim is filed in good faith and with a reasonable basis pursuant to § 15(e)(1), even though the claim is found to be untimely under § 16(a)(2)?

---

* The Vaccine Act, which established the National Vaccine Injury Compensation Program, is codified at 42 U.S.C. §§ 300aa-1 *et seq.* For convenience, future references will be to the "Vaccine Act," the "Act," the VICP, or the "Vaccine Program." Individual sections of the Act referenced in text will include only the section number.

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STATEMENT OF INTERESTS OF *AMICI CURIAE*

Amici are groups that have been involved in the National Vaccine Injury Compensation Program ("VICP") for many years and see great value to the VICP of having attorneys involved in the often complex cases, factual and legal.[1]

Amicus curiae the National Vaccine Information Center ("NVIC"), founded in 1982 by parents whose children suffered injury or death following DPT vaccinations, is widely recognized as the oldest, largest, and most effective non-profit national organization advocating for the institution of vaccine safety and informed consent protections in U.S. health programs. NVIC has assisted thousands of individuals who have suffered serious health problems, hospitalizations, injuries, and deaths following vaccinations. It promotes scientific research to evaluate vaccine safety and defends the ethical principle of informed consent for medical interventions, including vaccination, which carry a risk of injury or death.

Amicus curiae the Vaccine Injured Petitioners Bar Association ("Petitioners Bar") is a voluntary bar association composed of attorneys who represent petitioners in the VICP. Members of the Petitioners Bar

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1. Pursuant to Sup. Ct. R. 37.6, *amici* note that no part of this brief was authored by counsel for any party. *Amici* also note that no party or counsel made a monetary contribution intended to fund the preparation or submission of this brief, and that no person or entity other than *amici* or their members made such a monetary contribution. This brief is filed with the consent of all parties.

have assisted the families of children and adults who have suffered adverse reactions to vaccinations since the inception of the VICP. The organization and its members have a professional responsibility to ensure that the families of the vaccine-injured receive justice as Congress intended – swiftly, and with generosity and certainty.

To that end, members of the Petitioners Bar have testified before Congress on numerous occasions concerning vaccine injuries and the VICP. It is in the performance of their professional duties that the attorneys in the Petitioners Bar have seen, and continue to see, many injured individuals who have potential vaccine injury claims, but who cannot bring them on their own, without a lawyer, due to the medical and/or legal complexities of their cases.

Amicus curiae The George Washington University Law School Vaccine Injury Clinic ("Vaccine Injury Clinic") represents the families of young children and adults in the VICP. Through the efforts of its Student-Attorneys and faculty, the Vaccine Injury Clinic has obtained compensation for children with severe mental and physical disabilities and has prevailed in appeals to the United States Court of Appeals for the Federal Circuit on significant vaccine issues. The Vaccine Injury Clinic has also advocated before the Department of Health and Human Services for modifications to the Vaccine Act, and has submitted detailed comments on the Rules and the Guidelines applicable to cases brought under the Act.

SUMMARY OF ARGUMENTS

While there may be circumstances where rejecting an untimely claim in the Vaccine Act is justified because it is not found to be filed in good faith and without a reasonable basis, attorneys' fees should not be denied simply because a claim is deemed untimely. The test that Congress intended and that is clearly set forth in the statute is found at §15(e)(1), where attorneys' fees are allowed "if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought." In other words, a claimant[2] does not have to prevail on the claim to receive attorneys' fees, and nothing in the statute suggests the denial of attorneys' fees if a claim is ultimately found untimely when the claim is reasonable and brought in good faith. Also, contrary to the dissenting opinion, the Vaccine Act is not a "fee shifting" statute because the notion that "the prevailing party [pays] the losing party's attorneys' fees" is incorrect. The majority correctly characterized the Vaccine Act as a remedial compensation program and not a waiver of sovereign immunity, and the dissent's reasoning would lead to absurd results.

In order for the VICP to be successful for remedial compensation, it is important that claimants have access to competent counsel without having to worry about paying attorneys' fees and costs if they are unsuccessful in the program. As the *en banc* majority decision correctly

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2. To avoid confusion, Petitioners in the Vaccine Injury Compensation Program (VICP) will hereinafter be referred to as Claimants, and the Respondent in VICP claims will be referred to as the Secretary or the Government.

observed: "Congress recognized that having to shoulder attorneys' fees could deter victims of vaccine-related injuries from seeking redress." *Cloer v. Sec'y of Health & Human Services*, 675 F.3d 1358, 1362 (Fed. Cir. 2012).

Contrary to the protestations of the Secretary of Health and Human Services (hereinafter "the Secretary") and the concerns of Judge Bryson in the dissent, determining whether a claim was brought in good faith and with a reasonable basis is not an onerous or difficult undertaking. Nor will it result in a great number of unnecessary and expensive proceedings. However, denying attorneys' fees and costs, as argued by the Secretary, will result in the wholesale denial of competent counsel to numerous claimants with legitimate claims. Further, a reversal of the lower court's decision would shift the financial burden to the claimants and other results that are contrary to Congress' clear intent.

The Vaccine Act, which was intended to be claimant-friendly, non-adversarial, generous and expeditious, has certainly been successful in reducing civil litigation, assuring vaccine supplies, and preventing any meaningful discovery into potential adverse effects of vaccines. Further, the VICP has accomplished these goals with extremely low transaction costs. Although a short statute of limitations has excluded many injured victims from seeking compensation for their injuries, reversing the prior en banc decision will prevent even more petitioners from seeking compensation even though the onset of an injury is a matter of medical opinion. A number of examples are provided to assist the Court in understanding the complexities of these cases.

ARGUMENTS

A. THE LEGAL ARGUMENTS AGAINST RULING FOR THE SECRETARY

1. Plain Reading of the Vaccine Act and Congressional Intent

The majority correctly interpreted the plain meaning of the Vaccine Act in holding that § 300aa-15 only requires a petition be brought in good faith and with a reasonable basis for an award of reasonable attorneys' fees. In this case, there was a reasonable basis for believing that the claimant could demonstrate that the petition was brought in a timely manner and in accordance with the statute. A Court of Appeals for the Federal Circuit panel said as much before being reversed by an *en banc* decision. *Cloer v. Sec'y of Health & Human Services*, 675 F.3d 1358, 1362 (Fed. Cir. 2012).

Section 300aa-15(e) states that reasonable attorneys' fees "incurred in any proceeding" must be awarded if a petition was filed under § 300aa-11. 42 U.S.C.A. § 300aa-15. Even if the Court declines to award compensation for the claimant's injuries, reasonable attorneys' fees "incurred in any proceeding" are still available, provided that the petition was "brought in good faith and there was a reasonable basis for the claim." *Id.* In defining "proceeding," § 300aa-11(a)(1) states that "a proceeding . . . *shall* be initiated by service upon the Secretary and *the filing of a petition*." 42 U.S.C.A. § 300aa-11(a)(1) (emphasis added). Applying a plain language interpretation of the statute, a "proceeding" does not exist until the filing of a petition, and § 300aa-11 has no language that limits a

"proceeding" to only *timely* filed petitions. 42 U.S.C.A. § 300aa-11. The use of the word "shall" eliminates discretion in the application of the provision: a proceeding *must* begin when the petition is filed and served. *Id.* Further, the plain language of § 300aa-15(e) stipulates that reasonable attorneys' fees are available, whether or not the compensation is ultimately awarded, for any § 300aa-11 proceeding as long as it is filed in good faith and with a reasonable basis. 42 U.S.C.A. § 300aa-15(e). Thus, according to the plain language of the Act, a proceeding must begin once the petition is filed, and the only requirements for receipt of attorneys' fees are that the petition was filed in good faith and with a reasonable basis. There is no mention of a timeliness requirement in either § 300aa-11 or § 300aa-15, and demanding good faith and a reasonable basis accounts for indefensibly late petitions because there can be no reasonable, good faith basis. Whether or not reasonable attorneys' fees *should* be awarded is addressed in the following sections, but whether they *can* be provided is plainly written into the relevant provisions of the Act.

The Secretary's claim that "under the most straightforward reading . . . an award of attorneys' fees and costs is unavailable when the petition is dismissed as time-barred," is incorrect. Petition for a Writ of Certiorari at 15, *Sebelius v. Cloer*, No. 12-236 (Aug. 22, 2012). The Secretary's "straightforward reading" references § 300aa-16(a)(2), the Act's statute of limitations period, yet neither § 300aa-15(e) nor § 300aa-11 is included in the Secretary's analysis. *Id.* at 11; 42 U.S.C.A. § 300aa-11, 15. Section 300aa-16(a)(2) states that "no petition may be filed for compensation" after expiration of the statute of limitations but is silent on the subject of attorneys' fees.

42 U.S.C.A. § 300aa-16(a)(2). Further, Congress chose not to condition the availability of *attorneys' fees* on timeliness of a petition, and § 300aa-11 only references § 300aa-16 with regards to filing a civil suit outside the VICP. 42 U.S.C.A. § 300aa-11(a)(2); Brief for the Respondent in Opposition at 6, *Sebelius v. Cloer, petition for cert. filed*, No. 12-236 (Aug. 22 2012). Thus, the Government's assertion that § 300aa-16 is a "statutory prerequisite" for obtaining attorneys' fees cannot be correct. Petition for a Writ of Certiorari at 15, *Sebelius v. Cloer*, No. 12-236 (Aug. 22, 2012).

The Government proposes that dismissed, untimely petitions are not petitions at all because § 300aa-16(a)(2) states that "no petition may be filed for compensation" after the applicable time period. 42 U.S.C.A. § 300aa-16(a)(2). Even if the Government's tortuous interpretation of the statute had merit, § 300aa-16(a)(2) does not explicitly prohibit the awarding of attorneys' fees in proceedings where petitions are ultimately deemed untimely. *Id.* Section 300aa-16(a)(2) states that, outside the stipulated time period, "no petition may be filed *for compensation*." *Id.* (emphasis added). However, section 300aa-15 distinguishes between "compensation" and reasonable attorneys' fees. 42 U.S.C.A. § 300aa-15. Section 300aa-15(e)(1) explicitly states that even where a "petition does *not award compensation*" the court may still award reasonable attorneys' fees. 42 U.S.C.A. § 300aa-15(e)(1)(B) (emphasis added). Also, where compensation is granted, the court must "*also* award" reasonable attorneys' fees incurred. 42 U.S.C.A. § 300aa-15(e)(1) (emphasis added). The statutory language provides that compensation for injuries is separate from attorneys' fees, and it is possible to reimburse claimants for their attorneys' fees

even if they do not receive compensation. Thus, there is a distinction between 1) construing the provision to state that petitions filed for the express purpose of receiving compensation cannot be filed outside the applicable time period, the Secretary's position, and 2) interpreting the provision to simply state that an untimely petition cannot receive compensation. The latter interpretation still allows for the award of attorneys' fees, which are distinct from compensation for injuries, as long as no other statutory provisions were violated. Further, the latter reading of the statute would allow § 300aa-15, §300aa-11, and §300aa-16(a)(2) to coexist without contradiction while eliminating the confusion stemming from the Dissent's attempt to distinguish "filing a petition" under §300aa-11 and a "petition filed" under §300aa-15(e). *Cloer v. Sec'y of Health & Human Services*, 675 F.3d 1358, 1363 (Fed. Cir. 2012).

2. The Secretary's Position that § 300aa–15(e)(1) is a Fee-Shifting Statute that Should be Construed Narrowly is Unavailing

The Secretary's interpretation of the attorney's fee provision under § 300aa–15(e)(1) is inconsistent with the VICP. *See Cloer v. Sec'y of Health & Human Services*, 675 F.3d 1358, 1364 (Fed. Cir. 2012). Contrary to the Secretary's interpretation, the Vaccine Act is a remedial compensation statute, not a fee-shifting statute. The Vaccine Act is more analogous to a common fund provision, which is a separate exception to the "American Rule." Even assuming *arguendo* that § 300aa–15(e)(1) is a fee-shifting statute, it cannot be construed to yield an absurd result: that being that neither the Federal Court of Appeals nor the Court of Federal Claims had jurisdiction over Dr. Cloer's petition. Thus, even if this Court is inclined to

strictly construe § 300aa–15(e)(1), it should follow Judge Reyna's plain meaning construction of § 300aa–15(e)(1) as laid out in the majority's opinion below.

a. Section 300aa–15(E)(1) is Not a Fee-Shifting Statute, but is Part of a Remedial Compensation Act that Falls Under the Common Fund Exception to the "American Rule"

Section 300aa–15(E)(1) is not a "fee-shifting" statute in the traditional sense and is certainly not a statute where "the prevailing party will pay the losing party's attorneys' fees." *See Cloer v. Sec'y of Health & Human Services*, 675 F.3d 1358, 1364 (Fed. Cir. 2012). Rather, a more appropriate analogy is the common fund doctrine that establishes an exception the American Rule. *Trustees v. Greenough*, 105 U.S. 527 (1882).[3] The doctrine has been applied in many situations and expanded to funds created by legislative and administrative actions, like the Vaccine Fund. *See, e.g., Paris v. Metropolitan Life Ins. Co.*, 94 F. Supp. 792, 794 (S.D.N.Y. 1947) (upholding award of legal fees to attorney representing labor union before Regional War Labor Board regarding payments under New York insurance laws).

The common fund doctrine generally has three requisite elements: (1) a fund; (2) a court must be able

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3. *See also* John F. Vargo, *The American Rule on Attorney Fee Allocation: The Injured Person's Access to Justice*, 42 Am. U. L. Rev. 1567, 1578 (1993) (discussing each of the six exceptions); David A. Root, *Attorney Fee-Shifting in America: Comparing, Contrasting, and Combining the "American Rule" and "English Rule"*, 15 Ind. Int'l & Comp. L. Rev. 583, 584 (2005) (same).

to exert control over the fund; and (3) fund beneficiaries must be identifiable so the court can shift the attorneys' fees to those benefiting from the litigation. *See* John F. Vargo, *The American Rule on Attorney Fee Allocation: The Injured Person's Access to Justice*, 42 Am. U. L. Rev. 1567, 1581 (1993) (synthesizing the rule from common fund cases). Here, the Vaccine Fund indeed exists; the Court of Federal Claims regularly exerts control over the fund; and the fund benefits vaccine manufacturers and administrators, the Secretary, the claimants, and the public.. The three conditions of the common fund doctrine are therefore met, providing an exception to the American Rule.

In addition, the nature of the VICP validates the classification of § 300aa–15(e)(1) as falling under the common fund exception to the American Rule, not as a fee-shifting statute. The VICP was designed as a tort-reform program where vaccine injury claimants bring their petitions for compensation and the Secretary responds on behalf of the Government, who administers the Vaccine Fund. The Vaccine Fund was created and continues to be funded by a tax on vaccines. It is not paid from the United States general revenue. Fees are paid out of the Vaccine Fund, as are the fees and costs of the Respondent and the administrative costs of the Office of Special Masters. The VICP is intended to be a non-adversarial alternative to the highly adversarial tort litigation scheme between vaccine injury victims and vaccine manufacturers outside the program. The Secretary's role exists merely to assure that there is adequate evidence demonstrating the vaccine caused the alleged injuries. There is no determination of fault because the VICP is a no-fault scheme. When claimants in the VICP are unsuccessful in their claims, there are no "winners" and "losers" between whom fees

can be shifted back-and-forth, and, once again, it must be emphasized that the fund also pays for the fees and costs of the Department of Justice, the operating costs of the special masters, and the research and other costs of the Secretary.

For these reasons, the Secretary incorrectly analyzes § 300aa–15(e)(1) under the fee-shifting exception to the American Rule when, in fact, it is not a fee shifting statute at all, and if it were characterized as such, the common fund exception should apply in light of the nature of the VICP, and where clearly, this is not a fee shifting statute, but rather one where all of the transactions costs are paid from the fund.

b. The Secretary's Construction of Section 300aa–15(e)(1) Yields Absurd Results

Even if this Court entertains the Government's line of reasoning and agrees that § 300aa–15(e)(1) is a fee-shifting statute which requires strict construction, the Secretary's construction of the § 300aa–15(e)(1) yields absurd results, namely that neither the United States Court of Appeals for the Federal Circuit nor the Court of Federal Claims had jurisdiction over Dr. Cloer's petition.

This Court has pointed out that "a literal application of a statute, *which would lead to absurd consequences*, should be avoided whenever a reasonable application can be given to it, consistent with the legislative purpose." *United States v. Katz*, 271 U.S. 354, 357 (1926) (emphasis added). The majority in Cloer determined the Secretary improperly distinguishes between a "filing a petition" for purposes of § 300aa–11 and a "petition filed" for purposes of § 300aa–15(e). *Cloer v. Sec'y of Health & Human Services*, 675 F.3d 1358, 1363 (Fed. Cir. 2012).

The Secretary wants to interpret § 300aa–15(e) and other statutory provisions as providing that "an untimely filed petition is a 'petition' sufficient to commence proceedings but not a 'petition filed' for purposes of § 300aa–16 and § 300aa–12." *Id.* The Secretary's distinction between "petitions" and "petitions filed" leads to the absurd result that neither the Federal Circuit Court of Appeals nor the Court of Federal Claims had jurisdiction over Dr. Cloer's petition. *Id.*

Instead, the Court should follow the plain meaning construction of § 300aa-15(e)(1) in the majority's opinion below. *Id.* at 1361. The majority outlined in its opinion how the absence of an analogous reference to the statute of limitation in the attorney's fee provision suggests that Congress did not intend to require compliance with the statute of limitation as a prerequisite for the recovery of attorneys' fees. *Id.* This more reasonable construction is expressed in the following excerpt from the majority opinion below:

> "Nor does the plain language of § 300aa–11(a)(1) require that a petition be timely filed in accordance with § 300aa–16. By contrast, § 300aa–11(a)(2)(A), which refers to civil actions brought in state or federal court, does require the filing of a petition 'in accordance with section 300aa–16.' The absence of an analogous reference to § 300aa–16 in the attorneys' fees provision suggests that Congress did not intend to require compliance with § 300aa–16 as a prerequisite for the recovery of attorneys' fees."

Id.

Therefore, because the Secretary's construction of § 300aa–15(e)(1) yields absurd results, this Court should follow Judge Reyna's construction of § 300aa–15(e)(1) instead.

B. THE PRACTICAL EFFECTS OF RULING FOR THE SECRETARY

1. Ruling for the Claimant Will Not Result in the Consequences Predicted by the Secretary

The Secretary speculates that the majority opinion will lead to extensive shadow trials that will drain the court's time and resources, but these concerns are unsubstantiated in light of the fact that special master's already do most of the heavy lifting just to determine if a petition is timely. Petition for Writ of Certiorari at 12-16, 23-25, *Sebelius v. Cloer*, No. 11-832 (Dec. 21, 2011). Further, if the majority decision stands, attorneys have no incentive whatsoever to file untimely petitions without good faith or a reasonable basis because the current ethical and procedural guidelines currently provide sufficient deterrence. The Secretary's predictions are unsupported.

There are, however, genuine concerns for the VICP if the majority opinion is overturned by this Court. Denial of attorneys' fees in cases that, while filed in good faith and with a reasonable basis, are ultimately found to be untimely would lead many attorneys to turn down these cases and decrease participation in the program, while attorneys that remain in the VICP, where transaction costs are substantially lower than in traditional litigation, will be forced to shift costs to the claimants. Finally, a

reversal of the lower court would also lead to unintended consequences and increased litigation outside of the program, putting a strain on the judicial system but not in the manner expressed by the Secretary.

a. The Secretary's Concerns about "Shadow Trials" are Irrelevant and Unfounded

The Secretary has devoted much time and effort on the purported and speculative difficulties that might result from the Federal Circuit's decision below. Petition for Writ of Certiorari at 12-16, 23-25, *Sebelius v. Cloer*, No. 12-236 (Aug. 22, 2012). The Secretary warns that a petition filed after the statute of limitations will require special masters to conduct a "shadow trial" to determine whether the petition has a reasonable chance of succeeding if the claimant had made a timely filing. *Id.* at 13. The Secretary laments that such a collateral proceeding will require review of medical records, development of expert testimony, and briefing to the special master, all of which "would be wasteful, painful, and complex . . ." *Id.* (internal quotations omitted).

The Secretary's concerns cannot be reconciled with how the Vaccine Act works in practice. First, there is a distinction between "Table" and "non-Table" injuries. If a claimant has suffered a Table injury within a specified time frame after receiving a vaccine, the claimant is presumed to be entitled to compensation and the corresponding attorneys' fees. *See, e.g.*, §§300aa-11(c) (1) (C) (ii); 300aa-14; *Grant v. Secretary of HHS*, 956 F.2d 1144, 1147 (Fed. Cir.1992). Thus, in the case of an untimely Table petition, virtually the only question regarding attorneys' fees is whether there was a good faith basis for arguing either

that the limitations period had not run or that equitable tolling should excuse the untimeliness. In such cases, the special master must consider the underpinning facts in order to determine that the claim is time barred. Thus, in Table cases, no additional or burdensome "shadow trial" will be required to resolve whether the claimant nevertheless had a good faith or reasonable factual basis for bringing a petition outside of the limitations period.

The Secretary's "shadow trial" argument is not relevant with respect to non-Table claims either. There is no dichotomy between a special master's statute of limitations determinations and their analysis of the claim's merits. A claimant is required to prove "cause in fact" to recover on a non-Table vaccine injury. *See, e.g.*, 42 U.S.C.A. § 300aa-11(c)(1)(C)(ii); *Grant*, 956 F.2d at 1147-48. When evaluating timeliness, the special master must determine whether a petition has been filed "after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of [a vaccine-related] injury. 42 U.S.C.A. § 300aa-16(a)(2). This requires the special master to determine what that injury is, whether it was caused by a vaccine, and its symptoms, manifestations, and/or aggravations. Thus, to determine when the statute of limitations has expired, the special master must consider in detail the facts underlying the merits of that claim.

The case at bar is illustrative of this very point. The chief special master correctly noted that "the sole issue presented at this stage of the proceedings is whether Dr. Cloer's Petition . . . was filed after 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury."

42 U.S.C.A. § 300-aa-16(a)(2); *Cloer v. Sec'y of Health & Human Services*, No. 05-1002V, 2008 WL 2275574 at *10 (Fed. Cl. May 15, 2008). And yet, the decision necessarily went into minute detail about the nature of Dr. Cloer's injury, her medical history, and diagnosis, the expert testimony submitted in support of her petition and host of other matters. *Cloer v. Sec'y of Health & Human Services*, No. 05-1002V, 2008 WL 2275574 (Fed. Cl. May 15, 2008). It was only "[a]fter considering the entire record and the parties' respective arguments," that the chief special master was in a position to conclude that "this case must be dismissed as untimely." *Id.* at *10.

b. A Ruling in the Claimant's Favor Will Not Increase Untimely Vaccine Act Petitions

The Secretary also erroneously states that a decision in the claimant's favor will lead to an "increase in the number of untimely Vaccine Act petitions." Petition for a Writ of Certiorari at 24, *Sebelius v. Cloer*, No. 12-236 (Aug. 22, 2012). The Secretary's assertion is contrary to the language of § 300aa-15(e)(1), which discourages the VICP bar from bringing claim unless they are brought in good faith and with a reasonable basis. There is no advantage for the claimant to file an untimely claim because the special master will not award any recovery, fees, or costs if this standard is not met., so there is no risk that there will be an increase in untimely petitions, much less a drastic increase.

Moreover, vaccine injury lawyers are already bound and guided by the requirements of the Federal Rules of Civil Procedure (FRCP), the Rules of the United States Court of Federal Claims (RCFC), and the Rules of

Professional Conduct. If the VICP attorney disregards FRCP Rule 11(b) and brings untimely petitions in bad faith, the special master has the authority to impose Rule 11 sanctions. Additionally, attorneys are held to their states' respective Rules of Professional Conduct and are ethically obligated not to bring a claim "unless there is a basis in law and fact for doing so that is not frivolous .. . ." MODEL RULES OF PROF'L CONDUCT R. 3.1 (2012).

Allowing legitimate claims to be filed furthers the goals of justice. All of the rules mentioned above allow non-frivolous and good faith arguments for "extension, modification, or reversal of existing law." *Cloer v. Sec'y of Health & Human Services*, No. 05-1002V, 2008 WL 2275574 at *10 (Fed. Cl. May 15, 2008). And yet, the decision necessarily went into minute detail about the nature of Dr. Cloer's injury, her medical history, and diagnosis, the expert testimony submitted in support of her petition and host of other matters. *Cloer v. Sec'y of Health & Human Services*, No. 05-1002V, 2008 WL 2275574 (Fed. Cl. May 15, 2008). There is an inherent belief in the legal system that case law develops by accretion and the law evolves because lawyers argue for change. This is evident within vaccine jurisprudence as well. *See Zatuchni v. Sec'y of Health & Human Services*, 516 F.3d 1312, 1321 (Fed. Cir. 2008) (holding that eligible claimant's estate which established vaccine-related injuries and vaccine-caused death was entitled to recover both death benefit and compensation for injury). Without this tenet, groundbreaking cases would be impeded, pivotal shifts in American jurisprudence would be less likely, and the law may never evolve in the favor of justice. *See generally Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012); *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310

(2010); *Printz v. United States*, 521 U.S. 898 (1997). Surely the government does not want to discourage participation in the VICP, and efforts should be made to develop and maintain the claimant-friendly program Congress had in mind when writing the Vaccine Act. *See* H.R. Rep. No. 99-908, pt. 1, at 3-7.

The Secretary's contention that the Court finding in favor of the claimant will likely lead to an increase in untimely vaccine petitions is unsubstantiated conjecture. To assume otherwise is to assume that the VICP bar is willing to disregard § 300aa(15)(e)(1), the Federal Rules of Civil Procedure, the Rules of the Court of Federal Claims, the Rules of Professional Conduct, and the probability of being sanctioned by the special master.

2. Ruling for the Secretary Will Result in Significant Unintended Consequences

a. Prohibiting Payment of Attorneys' Fees Will Result in Decreased Participation by Competent Counsel and an Increased Financial Burden for Claimants

Ruling in favor of the Secretary will discourage attorney participation in the VICP and result in an increased financial burden for claimants pursuing compensation in the VICP. Such an outcome will damage the integrity of the VICP. The former scenario will require untrained claimants to navigate the VICP's procedural, legal and medical complexities on their own, and the latter will discourage injured persons from pursuing compensation due to the financial burden.

Access to competent counsel is integral to the ongoing success of the VICP. Although originally intended to be simple enough to allow a claimant to pursue a claim *pro se*, the VICP has evolved both in procedural, legal and medical complexity such to render *pro se* claimants ineffective in pursuing these claims. The procedures for filing and adjudicating a vaccine claim are governed by the Vaccine Act, the Vaccine Rules adopted by the U.S. Court of Federal Claims, and the Guidelines for Practice adopted by the Special Masters. Peter Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 ADMIN. L. REV. 785, 795 (2011). These Guidelines for Practice require, *inter alia*, that a claimant submit comprehensive medical records to be organized in a highly specific manner. Office of Special Masters, *Guidelines for Practice Under the Nat'l Vaccine Injury Comp. Program* at 7. In fact, the special masters recognize that the complexity of the VICP necessitates the assistance of counsel and often recommend to claimants that they seek an attorney at the outset of the claim proceedings. In one case, an attorney attempting to represent his child was advised that he should seek the assistance of an attorney familiar with the complexities of the VICP, which have been well described by the special masters.[4]

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4. "Quite frankly, the special master deems respondent's contention that the Program is a rudimentary process to be offensive to petitioners who have faced increasingly difficult standards as a result of two administrative revisions of the Table; to those petitioners' attorneys who have dedicated their time and talent to the vindication of their clients' substantive legal rights; and to the special masters who have through years of effort developed the expertise in Program cases that Congress envisioned. If respondent believes truly that the Program is a rudimentary process, then one must question seriously why the government employs a cadre of experienced and well-compensated

Also, adjudicating a vaccine injury claim requires claimants to make difficult legal determinations and develop complex legal arguments. As mentioned above, claimants are required to include any materials that might be relevant when submitting their medical records. *Id.* at 5. Relevancy, no doubt, has its own legal standard that claimants may find difficult to ascertain without the assistance of counsel.

Likewise, most cases require claimants to prove causation. The straightforward "on-Table" cases make up less than 10% of petitions. The remaining 90% of cases are "off-Table," meaning the claimant must prove causation by enlisting medical experts to opine on causation.[5] Most

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attorneys, as well as a full complement of support staff, and why the government devotes abundant resources—presenting sometimes as many as three or four medical experts in a case, see, e.g., *Malloy v. Sec'y of Health & Human Services*, No.99-0193; *Franklin v. Sec'y of Health & Human Services*, No. 99-0855V--to defend so vigorously Program claims."

Rupert v. Health & Human Services, No. 99-0774, 2002 U.S. Claims LEXIS 294 at FN8.

5. See, *Stevens v. Health & Human Services*, No. 99-0594, where in a March 30, 2001 Ruling on Petitioner's Motion for Summary Judgment, then Chief Special Master Golkiewicz stated:

"With the enactment of the administrative Table amendments, effective March 10, 1995, there was a dramatic shift in the percentage of cases decided pursuant to the Table versus those decided under an actual causation theory. While possessing no empirical data, experience and anecdotal evidence suggest that the percentages flip-flopped; prior to the amendments 90% of cases were Table cases, while after the amendments 90% of cases were actual causation cases. In fact, the undersigned has yet to adjudicate a case involving the interpretation of the amended

pro se claimants will lack the required connection to the medical community to be able to secure an adequate expert opinion.

Claimants must also interact with both opposing counsel and the special masters in a manner that may be difficult without the assistance of counsel. Claimants are required to attend status conferences, file motions, and communicate with the court to resolve practical issues. It is, however, this interaction with opposing counsel that really makes attorney involvement in the VICP essential. There is an obvious imbalance in power and sophistication that favors the Government over the claimants. The Department of Health and Human Services and the Department of Justice both have greater access to funds, experts, and scientific data than the average claimant's attorney. This disparity is even more glaring when it is a *pro se* claimant against the federal government.

Attorneys are no less important in the context of the statute of limitations. As the Federal Circuit has noted, "[T]he purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field

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Table; all litigated claims have been causation cases. The acuteness of the problem is seen with newly added vaccines, such as the hepatitis B vaccine which was added to the Program in August of 1997. These vaccines are being added without the benefit of a multi-injury Table.11 Thus, practice has shown that virtually all of the cases proceed as causation-in-fact disputes. In fact, all 267 pending hepatitis B cases are causation claims. In the absence of clear guidance as to what proof is sufficient to establish a causation case, each case proceeds as a traditionally litigated case – that is, full blown litigation. Clearly, that is not what Congress intended when it designed the Program as an alternative to tort litigation."

bereft of complete and direct proof of how vaccines affect the human body." *Althen v. Sec'y of Health & Human Services*, 418 F.3d 1274, 1280 (Fed. Cir. 2005). The lack of this direct proof, combined with continually evolving science, further complicates determinations of when the limitations period has been triggered. In light of this difficulty, the role of the attorney is particularly important to facilitate the good faith debate. For these reasons, the Court should be careful not to impose fee restrictions that will further dissuade attorneys from participating in the VICP. (See *infra* n.9.)

Despite the important role of attorneys to the VICP, the VICP currently provides minimal compensation compared to most traditional liability attorneys. Over the course of the VICP's history, the Vaccine Trust Fund has paid $2.56 billion, accounting for both claimant compensation and attorneys' fees and costs. Statistics Rep. – Feb. 4, 2013, Nat'l Vaccine Injury Comp. Program, Health Res. and Serv. Admin., *available at* http://www.hrsa.gov /vaccine compensation/statisticsreports.html#claimscompensated (last visited Feb. 7, 2013). Of that amount, the Trust Fund has only awarded $163 million, or around 6.3% for not just attorneys' fees, but for both attorneys' fees and litigation costs. *Id.* Compare this with traditional civil litigation, where 1/3 of the compensation awarded would be paid to attorneys, in addition to reimbursement for costs, or even Federal Tort Claims Act litigation, where 25% contingent fee agreements are allowed. A decision for the government will further reduce the small number of attorneys willing to handle these claims.

A ruling for the Secretary will also shift the financial burden of pursuing compensation to the claimants. In

cases where there is any doubt about the date of onset that might affect the statute of limitations, claimants, if they are even able to do so, might be required to pay the costs of collecting records and hiring experts until the issue is resolved.[6] The Act provides that no attorney can charge any fee for services "*in connection with a petition filed under section 300aa-11*" in excess of the compensation awarded by a special master. 42 USC § 300aa–15(e)(3) (emphasis added). If the Court accepts the Secretary's argument that an untimely petition is not in fact a petition filed under § 300aa-11, it necessarily follows that the untimely petition would *not* be "a petition filed under section 300aa-11." Thus, it is conceivable that some attorneys, in addition to requiring claimants to pay

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6. In actuality, this issue may not always be capable of early resolution. The Claimant's burden of proof is the three-prong test in *Althen*. The third prong of that test is whether the onset of their injuries occurred within a medically-appropriate time-frame following vaccination. Therefore, the determination of onset is necessary in every causation-in-fact case. In one case that is currently on appeal at the Federal Circuit, and approximately ten years and two hearings after the petition was filed, the special master issued an opinion denying causation based on his subsequent determination of the "onset" of the claimant's injuries. He made these determinations despite the fact not one treating doctor in the medical records or claimant's expert supported his "finding", and despite the fact that one treating doctor even described the case in a medical journal as an injury following vaccination. The determination of the date of onset contrary to the medical records and treating doctors' opinions can easily result in a case becoming "untimely" after years of litigation. It will greatly expand what might be perceived as a "slight risk that can be quickly resolved" into a substantial risk that could affect the majority of claims in the program. *See also* the examples set forth at the end of this brief to further understand the complexities of these claims and the determinations regarding onset of symptoms.

the costs of pursuing a claim may require retainers to assure the payment of fees if a "petition" is found not to be a "petition." Judging attorneys' fees with the yardsticks of "reasonable basis" and "good faith" rather than timeliness will prevent this unfortunate scenario.

This shift of costs (and potentially even fees) from the Program to the claimants would be contrary to Congressional intent. Congress designed the VICP to relieve claimants of the onerous burden of contingency fees and extraordinary case expenses. *Id.* at 6 (noting that one of the flaws of traditional liability suits involves high transactions costs). It did so by providing that the VICP, rather than the claimant, would pay reasonable attorneys' fees for all petitions filed in good faith with a reasonable basis for the claim, regardless of the ultimate success of each petition. 42 U.S.C. 300aa-15(e)(1). The aforementioned prohibition against attorneys charging fees in excess of those awarded by the VICP was an additional measure to relieve claimants of financial burden. *Id.* §300aa-15(e)(3). These provisions clearly communicate Congress' intent to relieve claimants of the financial burden of filing a claim for compensation. Thus, the likely fee shifting that will result if the Court rules in favor of the Secretary will be in clear contrast to Congressional intent.

Congress intended for the Vaccine Act to relieve claimants of the burden and risk of paying attorneys' fees and costs. It did so by providing that the VICP, rather than the claimant, would pay reasonable attorneys' fees for all petitions filed in good faith with a reasonable basis for the claim, regardless of the ultimate success of each petition. 42 U.S.C.A. 300aa-15(e)(1).

3. Overturning the Lower Court's Holding Would Lead to Consequences Contrary to Congressional Intent and Not in the Best Interest of the Secretary

The Secretary argues a claim that is found to be untimely is, in effect, no claim at all. It is as if the claim was never filed. Adopting that reasoning may result in consequences that the Secretary has not completely considered. To understand these consequences, some explanation is necessary.

On August 1, 1997, two mercury-containing vaccines were added to the Vaccine Injury Table that resulted in children receiving seven additional mercury-containing vaccines during the first year of life. Prior to that time, the only mercury-containing vaccine was DPT. When a new vaccine is added to the Vaccine Injury Table, the act provides that, "If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the [VICP] . . . such person ***may*** . . . file a petition . . . not later than two years after the effective date of the revision," as long as the death or injury did not occur more than eight years before the Table revision. 42 U.S.C.A. § 300aa-16(b). (emphasis added). In other words, children who received Hepatitis B vaccines and Hib vaccines before August 1, 1997, and who were injured by those vaccines, did not have to file a claim in the VICP before filing civil suits against the administrators or manufacturers of the vaccines. Since the state statutes of limitations have not run on most of those cases, there are thousands of potential civil plaintiffs who are not time barred from filing civil lawsuits, and those lawsuits will

not be subject to this Court's ruling in *Bruesewitz*. *See Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011).

It is important for the Court to understand the differences between how Congress intended the VICP to function and how it is actually functioning today. A program that was designed to be petitioner friendly, informal, non-adversarial, generous and prompt is in fact none of those things. As noted *supra* n.7, the program is highly adversarial, and claimants are facing the resources of the Secretary and the Department of Justice without the benefit of meaningful discovery, knowing that their experts may be the subject of unnecessary published critiques that seem designed to discourage others from participating in the program. *See e.g.– Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009), *Porter v. Sec'y of Health and Human Servs.*, 663 F.3d 1242, 1249-50 (Fed. Cir. 2011). Even in cases where causation is conceded, the proceedings are often still protracted, and the very limited damages provided in the program are subjected to adversarial scrutiny and arguments that seem designed to pressure claimants to settle for less than to what they might otherwise be entitled.

This case, challenging the reimbursement of fees and costs in a case that was filed in good faith and with a reasonable basis because it was found to be untimely filed, represents yet another layer of complexity that the Secretary is trying to add to an already complex and difficult program that was meant to be simple and generous. Two examples are provided below, which hopefully will aid the Court in understanding the full ramifications of a decision in this case. In a claim currently being handled by

the Vaccine Injury Legal Clinic that was filed in July of 2004 by the Petitioner, *pro se*, the Secretary filed a report conceding "that the medical evidence demonstrates that [claimant] suffered encephalomyelitis as a result of her MMR vaccine and that her present condition is a *sequela* of that injury. Furthermore, there is not a preponderance of evidence that [claimant's] condition is due to factors unrelated to her MMR immunization. Accordingly, but for the timeliness of the petition, claimants would have been entitled to receive an award of compensation in this case." The Secretary moved to dismiss the claim saying that the claimant's parents had filed her claim one day too late. *Id.* After the clinic became involved in the case, a hearing was held where experts for both the claimant and the Secretary testified about whether the onset of symptoms was one day or the next day. In an order after the hearing, the special master concluded: "The undersigned having reviewed the entire record finds the Petition timely filed. In making this finding, the undersigned emphasizes that it was a difficult and very close determination." The special master agreed with petitioner's expert, and since causation was already conceded and agreed to by the expert for the Secretary, the case proceeded to the damages phase. Clearly, the case was filed in good faith and with a reasonable basis, and the claimant was entitled to compensation as well as reimbursement for attorneys' fees and costs. The clinic's decision to enter the case and represent the claimant was also made in good faith and with a reasonable basis. If the special master would have ruled against the claimant and concluded, as the Secretary urges this Court to conclude, that a claim was never filed, then not only would claimant not have received any compensation, but claimant would also not have been reimbursed for any costs incurred in pursuing the claim.

A hypothetical example that illustrates many of the points raised in this brief may be helpful. Jane Doe was born on January 10, 1997, and given a Hepatitis B vaccination the next day. She received the normal vaccinations scheduled for her 2 months, 4 months, and 6 months well baby visits. On January 20, 1998, despite the fact that she had a cold, Jane received the MMR vaccine. Seven days later, on January 27, she experienced a seizure and was rushed to the hospital, where she was admitted and prescribed medication for seizure control. After that, Jane's parents noticed that she was no longer as responsive and she lost the few words that she had started using. Over the next couple of years, Jane's parents complained to doctors that she was not meeting milestones and not developing like her older brother had. It was not until December of 2000 that a doctor suggested that Jane might be autistic, and when they asked him if the seizures after the MMR vaccination might have caused this, he said he did not know. Jane's parents did not find out about the availability of the VICP until January 26, 2001. After making some inquiries, they obtained the name of a lawyer who practiced in the VICP and called him. The lawyer immediately recognized that the statute of limitations was about to expire, and filed a claim that same day. Over the course of the next several months, the case worked its way through the VICP. All of the medical records were paid for and collected by Jane's parents, sent to the attorney, and filed. Jane's parents provided video of her as a baby to show how she went from being a normal baby prior to the MMR vaccine to a child who was now diagnosed with severe developmental delay. An expert for the Secretary reviewed the videos and concluded that Jane was exhibiting signs of autism in the videos taken before the MMR shot. He pointed to some flapping of

the arms and being unresponsive to the parents a couple times as evidence of this. Claimant's expert countered that these were normal baby movements, but even if there was something very mild going on, the MMR vaccine caused a significant aggravation of the condition. The Secretary's expert disagreed and gave the opinion that the cold Jane was experiencing when she was vaccinated continued and caused a fever, which then caused the seizure. While admitting that Jane experienced an encephalopathy seven days after the MMR vaccine, the Secretary's expert said it did not fit the definition of encephalopathy in the Vaccine Injury Table, so there was no presumption of causation for the claimant. The special master wrote a decision indicating that both experts were highly qualified, but she agreed with the respondent's expert that the MMR vaccine did not cause a significant aggravation of Jane's condition and that the onset was a couple months before the MMR vaccine. When an application for fees and costs was filed, respondent objected, arguing that a timely claim was never filed. The court agreed. The attorney decided that since a claim was never filed, and since he did not have to file a claim for injury from the Hepatitis B and Hib vaccines, he could now proceed with traditional civil litigation against the manufacturers of the Hepatitis B and Hib vaccines without having to worry about the restrictions on filing civil lawsuits imposed on claimants who have rejected the judgment of VICP and without having to worry about the ruling of the Supreme Court in *Bruesewitz*.

An alternative to this hypothetical scenario is that the claimant never filed a claim, because Jane's parents were inundated with her medical bills and could not risk pursuing a claim where they might not be reimbursed

for their attorneys' fees and costs. This is unfortunate, because had they filed the claim, a different special master would have heard the case and ruled that the video was not proof of an earlier onset and, even if it was, the MMR vaccine did indeed cause a significant aggravation of Jane's condition.

CONCLUSION

In conclusion, the Majority opinion in the lower court made the correct ruling when they found that attorneys' fees are still available on untimely petitions that were filed in good faith and with a reasonable basis. The plain language of the statute allows for the possibility of awarding attorneys' fees for petitions filed outside the limitations period, and the Act is a remedial statute, not a waiver of sovereign immunity, which obviates the need for narrow, strict interpretations of the provisions.

It is in the best interests of the Program, as well as Congress's intent, to remove financial concerns as an obstacle to file reasonable, good faith petitions, and overturning the lower court's holding will shift the financial burden to the claimants and reduce their access to experienced, competent counsel. Affirming the Federal Circuit decision will not result in an increase in unnecessary, expensive proceedings as the Secretary's concerns about "shadow trials" is overstated and the VICP program overall is characterized by extremely low transaction costs and much lower than average attorney compensation. The current statute of limitations has likely excluded many individuals from even filing petitions for their vaccine-related injuries, but a reversal by this Court would prohibit individuals whose petitions were filed

in good faith with a reasonable basis but ultimately an arguable onset from having their day in court and from being properly represented by counsel.

Respectfully submitted,

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